Oxicom 3000
INSTRUCTION MANUAL

WATERS MEDICAL SYSTEMS
P.O. BOX 6117
ROCHESTER, MN 55901-6117
Telephone: (800)-426-9877
(507) 252-3784
Fax: (507) 252-3700

CEpartner4U BV
Esdoornlaan 13
3951DB; Maarn NL.
+31 (0) 6-516.536.26

Caution: Federal law restricts this device to sale by or on the order of a physician.

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WATERS MEDICAL SYSTEMS

Customer Service

Waters Medical Systems provides toll-free telephone support to assist you with questions both technical and non-technical. Most problems can be diagnosed over the phone; however, if a representative needs to be called we can assist you. The toll-free number is also used to order instruments, parts, disposables and product information. Orders are also placed with a purchase order sent in on the Fax number shown below. When calling with a technical-related question, ask for technical support and your call will be directed quickly. All other questions can be directed to customer service.

Customer Service:

800-426-9877 (United States & Canada)
507-252-3784 (International calls)
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Returning Equipment

If we cannot resolve equipment problems over the phone, you may need to return your instrument to Waters. All items to be returned must be issued a RMA (Return Material Authorization) number in advance. This will prevent delays and possible refusal upon delivery. All parcels should be shipped to our street address. Correspondence can be sent to our post office box or use the Fax number above.

Parcels:
Waters Medical Systems
Attn: Medical Systems RMA#
2112 15th Street NW
ROCHESTER MN 55901

Correspondence:
Waters Medical Systems
Attn: Medical Systems
P.O. Box 6117
ROCHESTER MN 55903-6117

WATERS MEDICAL SYSTEMS QUALITY POLICY

Provide products and services that meet our customer's expectations, are defect free, and are delivered on time.

TABLE OF CONTENTS

SECTION	TITLE	PAGE
	Customer Support	**1**
1	**General Information**	**5**
	1.1 Introduction	7
	1.2 Benefits	7
	1.3 Theory of Operation	8
	1.4 Accuracy Limitations	8
2	**Operating Controls**	**11**
	2.0 Operating Controls	13
	2.1 Front Panel Controls	13
	2.2 Back Panel Controls	15
	2.3 DC-80 Disposable Cuvette	15
3	**Operating Instructions**	**17**
	3.1 Sample Preparation & Blood Handling	19
	3.2 Power On & Warm-up	21
	3.3 Quality Control	22
	3.4 O_2 Saturation Mode	30
	3.5 O_2 Content Mode	31
	3.6 Heparinize Cuvette	35
4	**Calibration**	**37**
	4.1 Calibration Theory	39
	4.2 Blood Sample Preparation	40
	4.3 Determine Functional Oxygen Saturation	43
	4.4 Calibration	44
	4.5 Oxygen Content Capacity Adjustment	49
5	**Maintenance**	**53**
	5.1 Maintenance Schedule	55
	5.2 Quality Control Filters - Cleaning	55
	5.3 Sample Chamber Cleaning	55
	5.4 Factory Default Settings	57
	5.5 Error Codes	59
	5.6 Erroneous Readings	62
6	**Appendix**	**66**
	Oxicom-3000 Specifications	68
	Abbreviations	70
	Equations	71
	Worksheets	72

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SECTION 1
GENERAL INFORMATION

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INTRODUCTION

The Waters Medical Oxicom 3000 Whole Blood Oximeter is designed for today's busy cardiac catheterization laboratory requirements and standards. The Oxicom 3000 will provide accurate, repeatable saturation measurements in less than ten seconds and will automatically compute AVO_2 difference, if the patient's hemoglobin has been entered.

The Oxicom 3000 optically measures the light absorption of the blood to measure functional oxygen saturation. Blood is infused into a safe, convenient, single-use, disposable cuvette. No special cleaning solution, calibrator, or tubing is required.

1.2 BENEFITS

The Oxicom 3000 uses the latest fiberoptic technology and a solid state detector to provide accurate and repeatable oxygen saturations. In the oxygen saturation mode, the Oxicom 3000 will provide results in less than 10 seconds.

For convenience and accuracy in determining cardiac output by the Fick method, the Oxicom 3000 measures oxygen saturations of arterial and venous samples and calculates content and AVO_2 difference. Simply input the patient's hemoglobin and insert the arterial and venous samples and the Oxicom 3000 will automatically compute the AVO_2 difference.

Contact with blood and contaminated waste products is virtually eliminated with the Oxicom 3000. Blood samples are injected into a sealed, single-use disposable cuvette which is easily inserted into the sample chamber located on the front panel. After the sample is measured, the cuvette and syringe are disposed with other hospital wastes.

CAUTION:

Be sure that the cuvette and syringe are disposed of in a manner consistent with good hospital practices for infectious materials.

The introduction of fiberoptic technology has eliminated the need for maintaining tubing or pumps with the Oxicom 3000. No zeroing or calibration solutions are required.

The Quality Control (QC) filters supplied with your Oxicom 3000 allows the user to check the calibration of the Oxicom 3000. The set of filters consist of one translucent plastic filter (QCl), and two precision glass filters (QC2 and QC3).

The optical densities of these filters are stored in the unit's microprocessor. When inserted into the sample chamber the Oxicom 3000 measures the optical density and compares it to the value stored. If the optical densities match the display will read a %Sat value. After affirming that the Oxicom 3000 is calibrated, the unit is ready to use.

Liquid control samples are also available but can not be used to calibrate in place of whole blood.

1.3 THEORY OF OPERATION

The Waters Oxicom 3000 is a Whole Blood Oximeter with the capability to measure functional oxygen saturation, calculate oxygen content and AVO_2 difference (Arterial, Venous Oxygen content difference). The Oxicom 3000 measures functional oxygen saturation of a 0.5 ml sample of whole blood. Then, using the patient's total hemoglobin level, it will calculate the oxygen content of that sample.

The Oxicom 3000 uses a silicon photodetector and light emitting diodes (LED) mounted in a sealed housing within the instrument. The blood sample is contained in an optically clear, disposable cuvette. The blood-filled cuvette is inserted through the front of the instrument into the sample chamber housing. BLOOD IS NOT INFUSED INTO THE UNIT.

The optical density of the sample is measured using two pulsed LEDs and one photodiode. The Oxicom 3000 system is designed to pulse on the infrared (IR) LED, and measure the optical density at 805 nm (manometers). Alternately, the red LED is turned on and measures the optical density at 660 nm. The photodiode converts the light transmitted through the blood filled cuvette into a current proportional to the amount of incident light. The current is processed by the microprocessor and the functional $\%O_2SAT$ is calculated by the Oxicom 3000. When the Oxicom 3000 is in the Content mode it will also calculate and display the arterial and venous content along with AVO_2 difference.

The amount of IR light absorbed by the blood is relatively independent of the blood's oxygenation. However, RED light absorption or optical density , is strongly dependent on the oxygen saturation. The ratio of the optical densities at the two wavelengths is used to calculate the functional oxygen saturation.

1.4 ACCURACY LIMITATIONS

LIPID SAMPLES:

Lipid (fat) particles in a blood sample may distort the normal light scattering and cause erratic readings.

HEPARIN AND SALINE:

Excess heparin and saline dilutes and lowers the hemoglobin of the sample. This artificially raises the percent saturation reading of the sample and can cause separation which further raise the percent saturation reading. Experience indicates samples with 10% or more liquid heparin or saline will affect the reading. Prior to withdrawing a sample of blood from any arterial line, the operator should aspirate 3-5 cc of blood from the line to remove any residual heparin or saline.

AIR BUBBLES:

Care should be taken to prevent oxygenation of the sample, always point the syringe and cuvette up. If micro bubbles are present, the oxygen saturation of the sample tends to rise 1-2%.

INTERFERING DYES:

Indocyanine (Cardio) Green, Evans Blue and Methylene Blue dyes absorb light at the same frequencies as blood. The presence of these dyes will effect oxygen saturation readings of the Oxicom 3000. Studies using interfering dyes must be run after blood samples have been taken to avoid erroneous readings.

OLD BLOOD SAMPLES:

Inserting the cuvette into the sample chamber within 10 minutes is recommended. If a delay is anticipated and clotting may begin, the syringe should be pre-coated with heparin.

CUVETTE HANDLING:

Care must be taken not to contaminate the optical path of the cuvette. Do not reuse cuvettes or the white plugs. Do not lay the cuvette on edge; this will increase the chance of blood separation. The clear sampling area should be laid face down.

CARBOXYHEMOGLOBIN and METHEMOGLOBIN:

The Oxicom 3000 is an oximeter which uses two wavelengths to determine the Functional Oxygen Saturation. Two wavelength oximeters such as the Oxicom 3000 cannot determine the amount of carboxyhemoglobin or methemoglobin. They can only determine the percentage of oxyhemoglobin as it relates to the total hemoglobin available for oxygenation.

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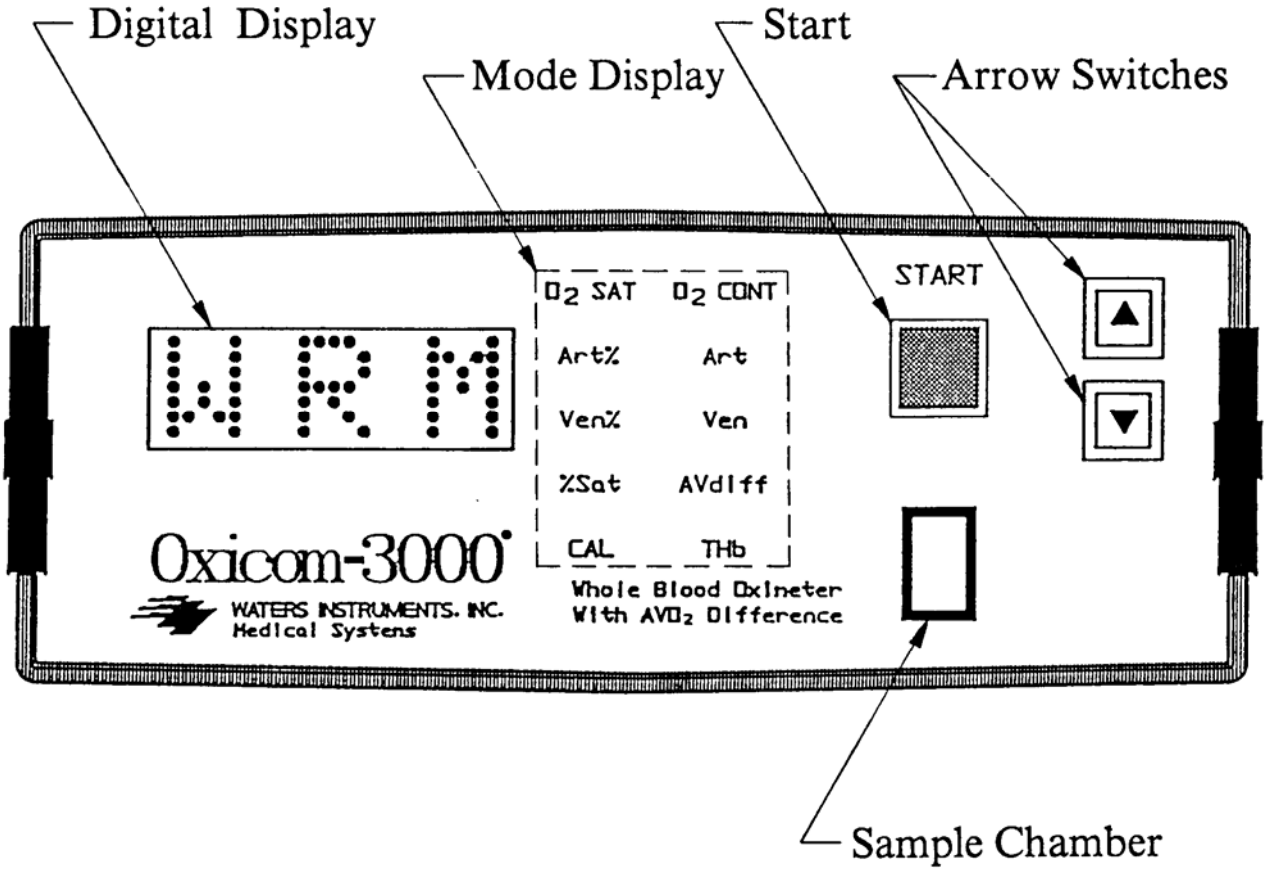
SECTION 2
OPERATING CONTROLS



Oxicom 3000 Front Panel
Operating Controls
Figure 2.1

2 OPERATING CONTROLS

This section describes the controls, displays and markings on the Oxicom 3000.

2.3 FRONT PANEL CONTROLS

DISPLAY: The measurement display consists of a three character display with two decimal points. Whenever the decimal points alternate positions the Oxicom 3000 is processing information. The display provides the user with the following information.

WRM - **W**a**RM**-up indicates that the Oxicom 3000 is in the timed 15 minute warm-up period.

RDY - **R**ea**DY** indicates the Oxicom 3000 is ready to accept blood samples. If the unit has been turned off and on again, you may bypass the warm-up by waiting 10 seconds and pressing START.

THb - **T**otal **H**emoglo**b**in. The THb can be entered by the user or the Oxicom 3000 will use the default value of 13.4, 13.6 or 13.9. To raise or lower the THb value, use the up or down arrow switches. Push the START button to enter the THb value into the microprocessor. The new value will be used for all future calculations or until the Oxicom 3000 is turned off. When the unit is turned on it will always show one of the default values 13.4, 13.6 or 13.9.

INS - **INS**ert instructs the operator to insert the cuvette.

RMV - **R**e**M**o**V**e, instructs the user to remove the cuvette or Quality Control Filters from the sample chamber.

ER1 - ER9 & **ERa - ERe** - **ER**ror Codes **l - 9** and **a - e** indicate the Oxicom 3000 was unable to measure the blood samples. Refer to Section 5.4 for more information.

OCC - **O**xygen **C**ontent **C**apacity. The OCC value is used to calculate the O_2 content. The factory set OCC is 1.34. To select 1.36 or 1.39, refer to section 4.7. The Oxicom 3000 will remind the user of the OCC value when in the O_2CONT mode. The default value for THb will be 10 times the OCC value.

***** - The * symbol followed by any number indicates that the %SAT value to be displayed exceeds 99.9%. Example: If the display reads *2.4 the actual value is 102.4.

Decimal Point - The two decimal points on the display indicate the magnitude of the reading and will alternately flash at one second intervals during balancing and calibration.

MODE DISPLAY: The Mode Display works in conjunction with the Mode Switch (O_2CONT/O_2SAT) on the back panel. Depending on the position of the Mode Switch, O_2SAT or O_2CONT will be lit on the front panel. When in the O_2SAT mode the O_2SAT and %Sat will function together. When in the O_2CONT mode the following indicators will function: Art%, Ven%, Art, Ven, AVdiff and THb.

O_2 SAT - The Oxicom 3000 is operating in the **O**xygen **Sat**uration mode. This mode measures the functional oxygen saturation of one sample and displays the value as %Sat.

%Sat - **% Sat**uration. The %SAT will light only when the mode switch is in the O_2SAT position. The display shows the functional oxygen saturation value of the blood sample.

O_2 CONT - The Oxicom 3000 is operating in the **O**xygen **CONT**ent mode. This mode measures the functional oxygen saturation of a single sample and calculates the oxygen content of that sample based on the user entered THb level. Then The Oxicom 3000 calculates the AVO_2 difference of two paired samples.

Art% - **Art**erial Oxygen Saturation percent (**%**). The Art% will light only when the unit is in the O_2 CONT mode. If the first sample's saturation value is above 85% SAT, the blood is assumed to be an arterial sample. If both samples are above 85% the higher will default to arterial, the lower to venous

Ven% - **Ven**ous Oxygen Saturation percent (**%**). The Ven% will light only when the unit is in the O_2 CONT mode. If the first sample's saturation value is lower than 85% SAT, the blood is assumed to be a venous sample. If both samples are below 85%, the lower will default to venous and the higher to arterial.

Art - **Art**erial Oxygen Content. The Art light indicates that the displayed reading is the arterial oxygen content of the blood sample.

Ven - **Ven**ous Oxygen Content. The Ven light indicates that the displayed reading is the venous oxygen content of the blood sample. The arterial or venous oxygen content is calculated by the %SAT (Venous or Arterial) multiplied by THb multiplied by 1.34.

%SAT (Venous) x THb x 1.34 = Venous Content

AVdiff - **A**rterial **V**enous **diff**erence. The AVdiff is the difference in oxygen content of the arterial and venous blood samples.

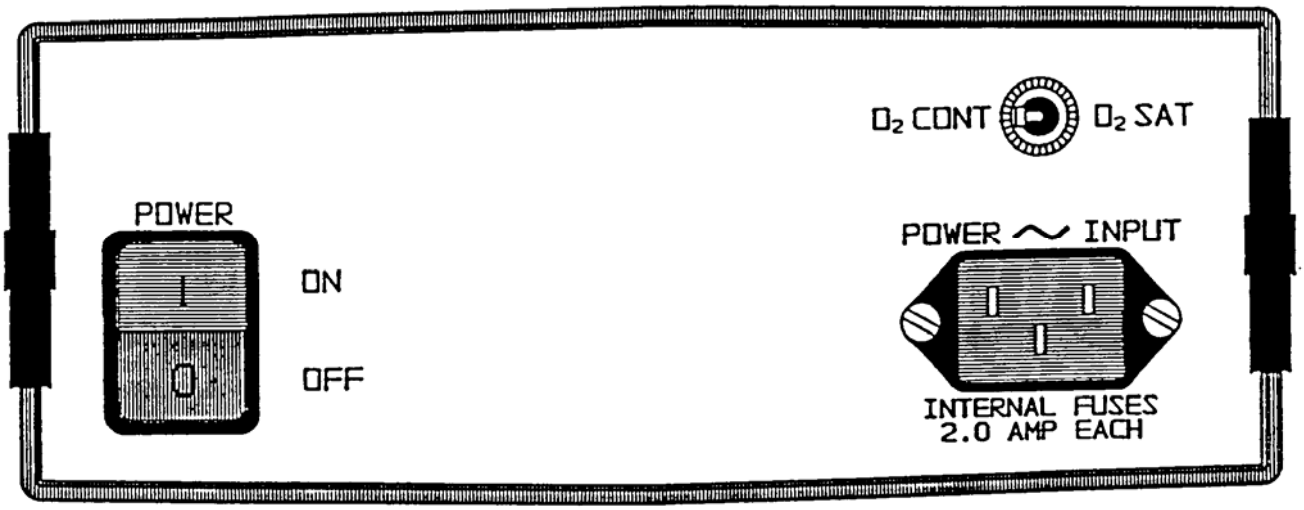
THb - **T**otal **H**emoglo**b**in. The THb indicator will light when the number being displayed is the total hemoglobin value to be used in the content calculation. The default value is 13.4. To raise or lower the value press the appropriate arrow switches.

CAL - The **CAL**ibration indicator will be lit when the operator has entered the calibration menu. Refer to the calibration instructions Section 4.

START - The **START** button is used to initiate blood sample measurements in both saturation and content modes. It is also used to lock into memory the total hemoglobin value when in the content mode. START also places the Oxicom 3000 in the calibration mode when depressed and the POWER switch is turned on.

Arrow Switches - The Up/Down Arrow switches are functional only in the content and calibration modes. In the content mode , the switches allow the operator to adjust the displayed value to the correct total hemoglobin value to be used during the test. The switches will also allow the operator to review each value shown on the mode display after an AVO_2 calculation. In the calibration mode, the operator will use the Arrows to adjust the displayed value to the correct functional saturation.

Sample Chamber - The disposable cuvette is inserted into the sample chamber. The display directs the user to INSert the cuvette. DO NOT INJECT BLOOD INTO THE SAMPLE CHAMBER.



Oxicom 3000 Back Panel
Operating Controls
Figure 2.2

2.2 BACK PANEL CONTROLS

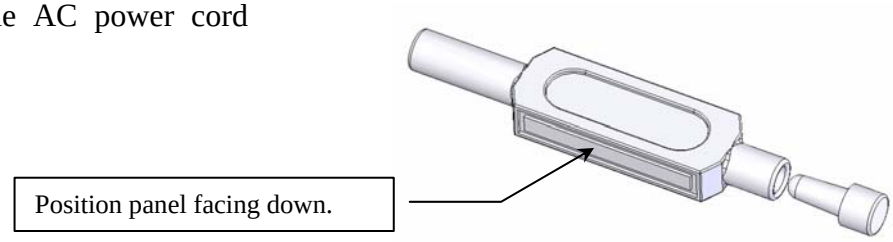
POWER - Switch applies AC power to the Oxicom 3000. When the Oxicom 3000 is turned On all the indicators on the front panel will do a self test. "WRM" will be displayed when completed.

O_2SAT/O_2CONT (Mode Switch) - This switch selects either **O**xygen **SAT**uration (O_2SAT) or **O**xygen **CON**tent (O_2CONT) mode of operation. If the mode switch is changed once a test has been initiated the test will be aborted.

POWER INPUT: Detachable AC power cord connection.

2.3 DC-80 DISPOSABLE CUVETTE

The DC-80 cuvette is used to hold the blood sample. It is a disposable single use device. Do not reuse the cuvettes or filters. The cuvette has a top and a bottom, a small panel indicates bottom and should always be inserted into the Oxicom downward. The porous filters come with the cuvettes and are to be mounted on the short neck of the cuvette. The filters allow air to pass through when the cuvette are being filled with blood, and prevent blood from spilling from the tip of the cuvette. The filters are also called cuvette caps, caps, or plugs.



Disposable Cuvette and Porous Filter
Figure 2-3

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SECTION 3
OPERATING INSTRUCTIONS

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3.1 SAMPLE PREPARATION AND BLOOD HANDLING

The Oxicom 3000 requires less than 0.5 cc of blood to measure blood oxygen saturation. The blood sample is withdrawn into a syringe. A disposable cuvette with filter is placed on the syringe. Blood is then infused into the cuvette and the cuvette is inserted into the Oxicom 3000 sampling chamber. Syringes and cuvettes are discarded after the sample has been measured.

The disposable Oxicom 3000 cuvettes are not heparinized. Therefore, the user must take the necessary precautions to prevent the blood sample from clotting. If the oxygen saturation of the blood sample is going to be determined within ten minutes of withdrawing, no heparin is required. If the sample is to be used for calibration of the Oxicom 3000, heparin is recommended, refer to Section 3.7.

For proper measurements, calibration and personal safety, it is essential that you follow these steps consistently.

HELPFUL HINTS:

All samples should be measured within ten minutes of withdrawal. The sooner the samples are measured the less likely the blood cells will separate.

Evacuate any air bubbles that remain in the syringe before mounting the cuvette. Air bubbles within the cuvette may alter the reading, especially during calibration.

Inspect the cuvette for cleanliness prior to use. Do not touch the sampling area (the clear surface) of the disposable cuvette. Handle the cuvette by their edges or tips.

Do not allow the cuvette to lie on the edge. Position the cuvette on the syringe so that when laid down, one of the cuvette side's face down. This will minimize any cell separation that may occur if the sample is not measured after withdrawal.

Place the porous filter (white plug) onto the disposable cuvette before infusing the blood from the syringe, except when calibrating the Oxicom 3000.

Do not force the blood sample into the cuvette. If a resistance is felt, discard and try another cuvette and filter.

Do not allow the filters to come in contact with any fluid prior to mounting on cuvette.

Do not reuse cuvettes or white plugs.

The sample must be mixed prior to inserting into the Oxicom 3000.

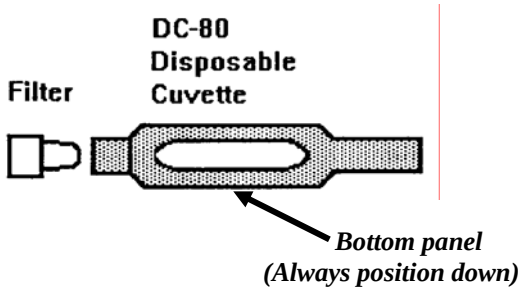
Samples diluted with saline or heparin will cause erroneous readings. All residual saline or heparin must be removed from the line before aspirating into the sample syringe.

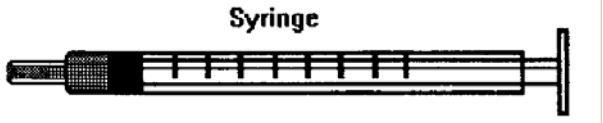
Cardiogreen dye and other dyes will effect the oxygen saturation reading. All saturation measurements must be made before dye injections are made.

SUPPLIES:
Disposable cuvette, one for each sample.
Porous filter, one for each cuvette.
Syringe, one for each sample.
Tissues or 4x4 gauze.

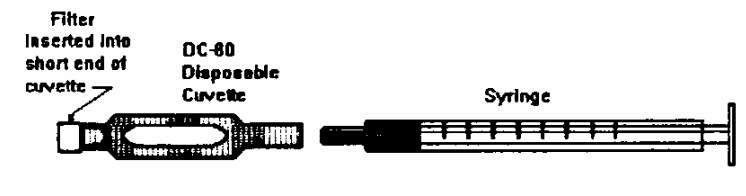
PROCEDURE

1. Prepare the cuvette and filters by mounting the filters onto the short end of the cuvette.



2. Flush or withdraw enough blood from the patient line in order to remove any saline. If the line is not properly flushed the sample will be contaminated and poor readings will result.

3. Withdraw 1 to 2 cc of blood from the line into the syringe. Evacuate any air bubbles that may be in the sample . If necessary, gently tap the syringe to knock any air bubbles loose.

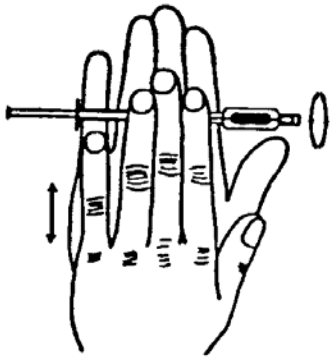
4. Mount and secure the long end of the cuvette onto the syringe.



5. Holding the cuvette and syringe vertically, slowly infuse the blood into the cuvette. Do not allow any air bubbles to adhere to the internal surface of the cuvette. Gently tap the cuvette if bubbles begin to develop.

6. The sample should be mixed by rolling the syringe between your hands in a horizontal position.

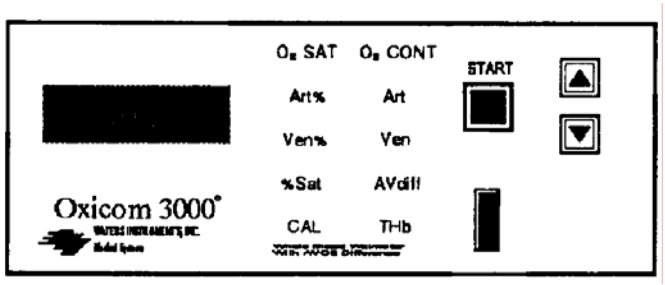
7. Proceed to Section 3.2 for instructions on measuring a blood sample.



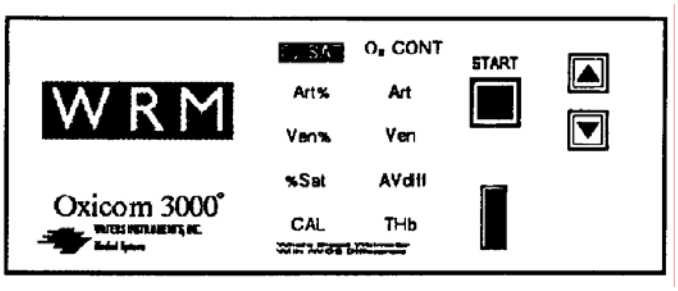
3.2 POWER ON & WARM-UP

USER ACTION

1. Turn the power switch (Back Panel) to the On position.



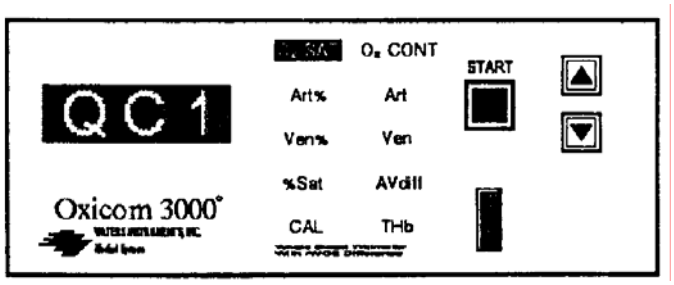
The Oxicom 3000 performs display and indicator checks.



The Oxicom 3000 requires a minimum warm-up period of 15 minutes. "WRM" will be displayed during the warm up period.

2. When the warm up period has been completed the display will show "QC1" for a moment then "INS" will be displayed. This indicates that the Oxicom 3000 is ready to perform the Quality Control (QC) procedure.

To perform the QC procedure proceed to Section 3.3, Step 1.



"QC1" momentarily displayed.

3.3 QUALITY CONTROL – Internal and External

The following instructions are continued from Section 3.2 Power On & Warm-up.

The Quality Control (QC) check allows the user to determine if the Oxicom 3000 is operating properly. The **Internal** Quality Controls consist of three filters, labeled QC1, QC2 and QC3. If the sample chamber is clean and the Quality Control's saturation readings are the same as when originally calibrated, the Oxicom 3000 will display a %Sat reading within 3%. ***For example***, if the correct reading for QCI is 85% the range the filter should read is between 82% and 88% (± 3%). If the optical densities of the QC filters are different or if the sample chamber is contaminated "ERe" will be displayed.

When "ERe" is displayed, clean the sample chamber and repeat the QC procedure, Steps 1-13 below.

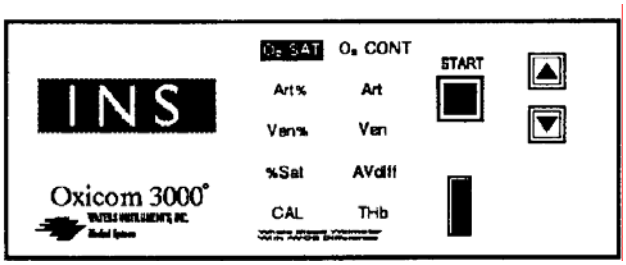
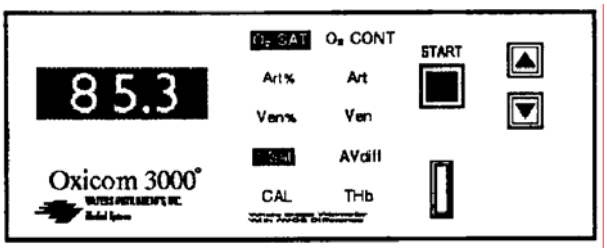
On page 72 there is a worksheet to record the daily QC readings. Please make copies for your records.

CAUTION

Do not insert the QC filters until "INS" appears on the display. If the QC filters are inserted before "INS- is displayed, "RMV" will be displayed. Remove the QC filter and wait for "INS" to appear.

NOTE

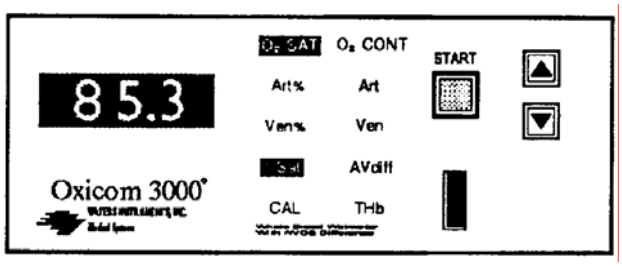
The Quality Control Filters must be inserted in sequence as instructed.

USER ACTION	Oxicom 3000 RESPONSE
1. When "INS" is displayed, insert QC1.	
2. Enter the reading for QC1 onto the worksheet.	

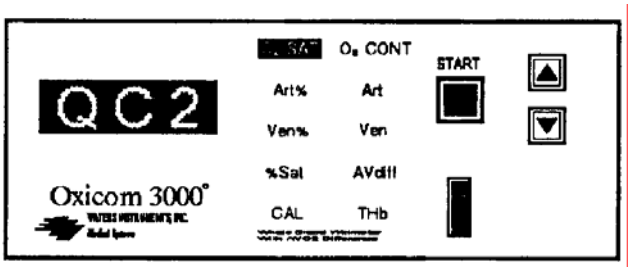
3.3 QUALITY CONTROL *Continued*

USER ACTION

3. Remove QC1, and the START button lights.

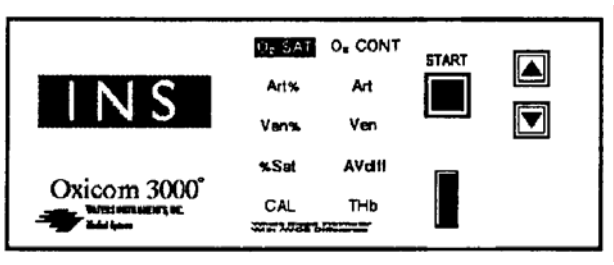


4. Press the START button and "QC2" will be displayed for a moment.

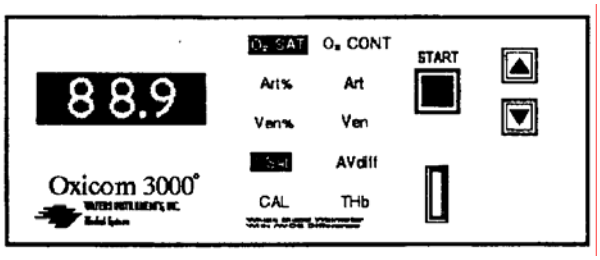


"QC2" momentarily displayed.

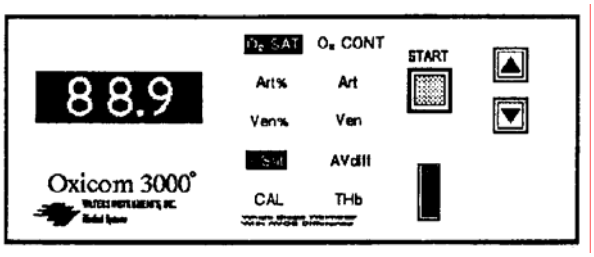
5. When "INS" is displayed, insert QC2.



6. The %Sat reading for QC2 will be displayed. Enter the value onto the worksheet.



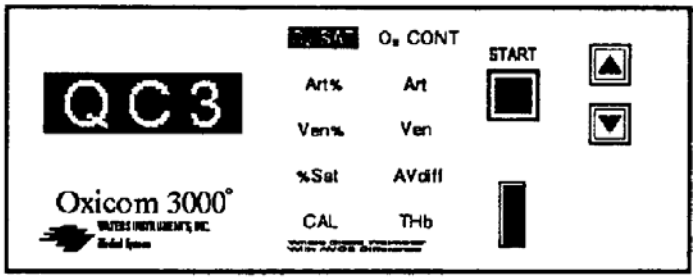
7. Remove QC2, and the START button lights.



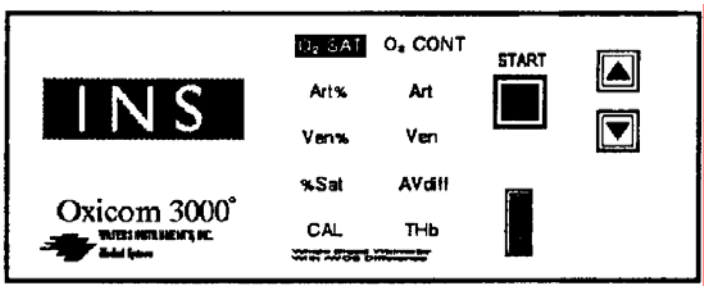
3.3 QUALITY CONTROL *Continued*

USER ACTION

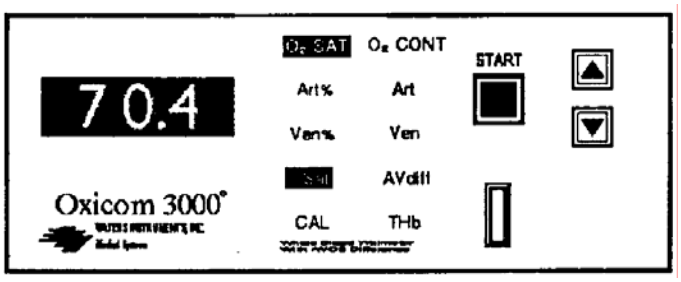
8. Press the START button and "QC3" will be displayed for a moment.



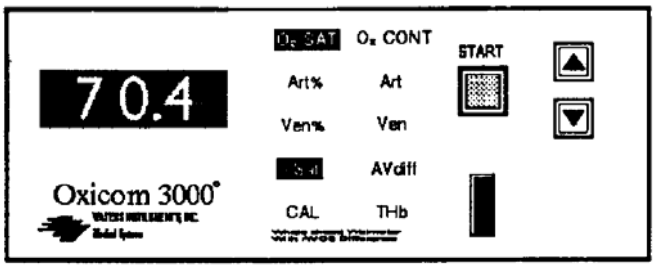
9. When "INS" is displayed, insert QC3.



10. Display will show %Sat for QC3. Enter the value of QC3 onto the worksheet.



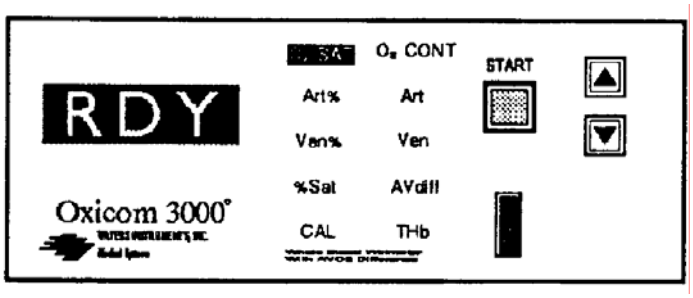
11. Remove QC3, and the START button lights.



3.3 QUALITY CONTROL *Continued*

USER ACTION

12. Press the Start button and "RDY" will be displayed. The Start button will be on.



13. Press the Start button. The Oxicom 3000 will be in the operating mode, ready to accept samples of liquid QC or blood.

When an error code is displayed refer to Section 5.5 Error Codes.

Upon repeating the test, if all filters indicate the correct %Sat, then the Oxicom 3000 is operating properly. However, if any of the QC filters displayed an incorrect value outside the ±3% range you should recalibrate the Oxicom 3000.

To measure O_2 saturation proceed to Section 3.4, Step 1.

To measure O2 content and calculate AVO_2 difference proceed to Section 3.5, Step 1.

Oxicom Internal QC Filter Worksheet

Use this worksheet to record your daily Quality Control readings

********** E X A M P L E ********** E X A M P L E **********

Oxicom 3000 S.N. 85786.251 Month: *January* Page 1 of 1

Last calibration: *October 2, 2000*

Filter:	QC1	QC2	QC3
Readings:	85.3	88.9	70.4
Range:			
From:	82.3	85.9	67.4
To: (±3%)	88.3	91.9	73.4

Location: *Cath Lab, E4*

The daily readings should be within 3% Sat of the readings entered above.

Daily record:

Date	QC1	QC2	QC3	Corrective Action	Initial
1/2/2001	85.5	89.0	70.5	*none required*	dmo
1/3/2001	85.5	88.9	70.5	*none required*	dmo
1/4/2001	85.4	89.1	65.6	*Due for calibration, talk to Jim at Bio-Med*	dmo

Worksheet Example

3.3 QUALITY CONTROL *Continued*

The following instructions are continued from Section 3.2 Power On & Warm-up but must be in the SAT RDY mode such as after the Internal QC's have been run and RDY appears.

The **External** Quality Control (liquid QC) check allows the user to determine if the Oxicom 3000 is operating properly and calibrated. The Quality Controls consist of three samples, labeled High, Mid and Low. If the sample chamber is clean and the Quality Control's saturation readings are the same as when originally calibrated, the Oxicom 3000 will display a %Sat reading within 7%. For example, if the correct reading for High is 85% the range the control should read is between 78% and 92% (± 7%). If the sample chamber is contaminated "CLN" or "RMV" can be displayed.

When ER's are displayed, clean the sample chamber and repeat, Steps 1-11 below.

On page 73 there is a worksheet to record the weekly liquid control readings. Please make copies for your records.

CAUTION

Do not insert the samples until "INS" appears on the display. If the samples are inserted before "INS- is displayed, "RMV" will be displayed. Remove the sample and wait for "INS" to appear. Also remember to insert cuvette with bottom panel on cuvette down.

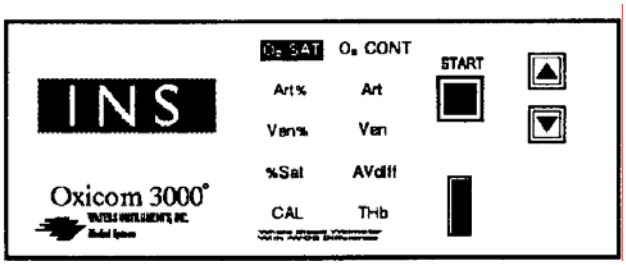
NOTE

The Liquid Quality Control samples should be inserted in sequence as instructed.

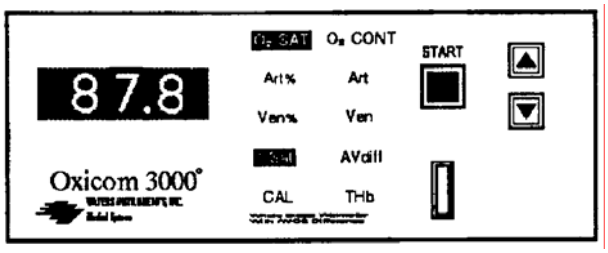
USER ACTION

Oxicom 3000 RESPONSE

1. When "INS" is displayed, insert High sample.



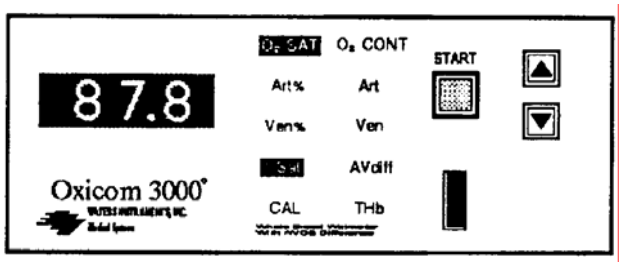
2. Enter the reading for High sample onto the worksheet.



3.3 QUALITY CONTROL *Continued*

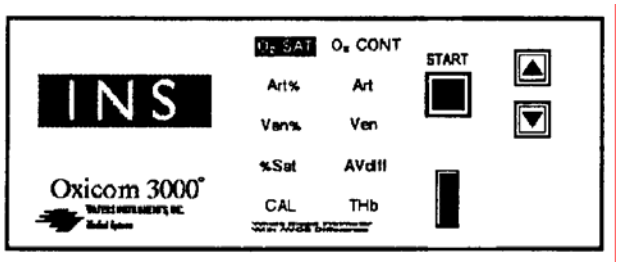
USER ACTION

3. Remove High sample, and the START button lights.

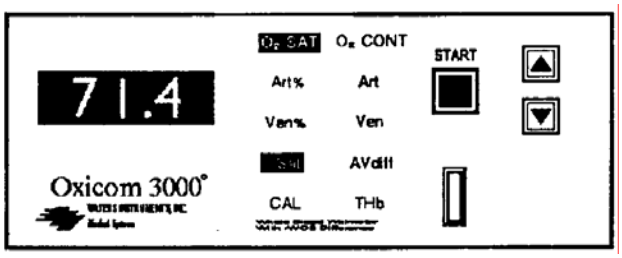


4. Press the START button and "INS" will be displayed.

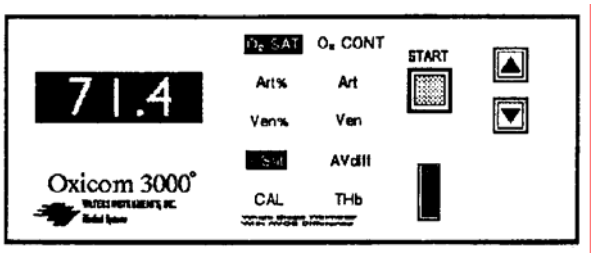
5. When "INS" is displayed, insert Mid sample.



6. The %Sat reading for Mid sample will be displayed. Enter the value onto the worksheet.



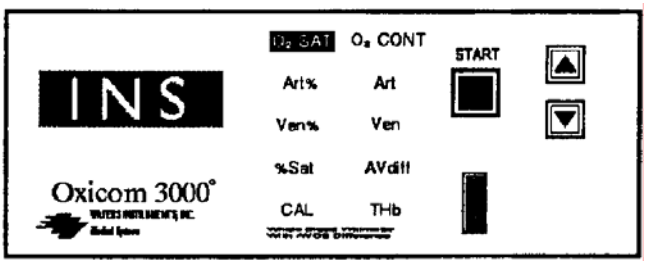
7. Remove Mid sample and the START button lights.



3.3 QUALITY CONTROL *Continued*

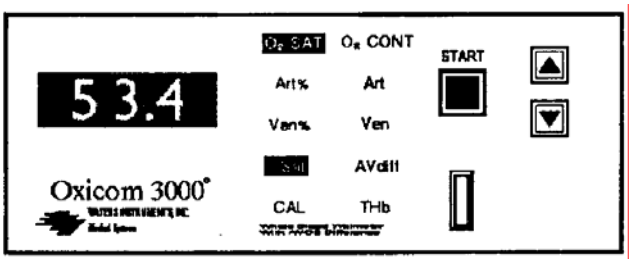
USER ACTION

8. Press the START button and “INS” will be displayed.

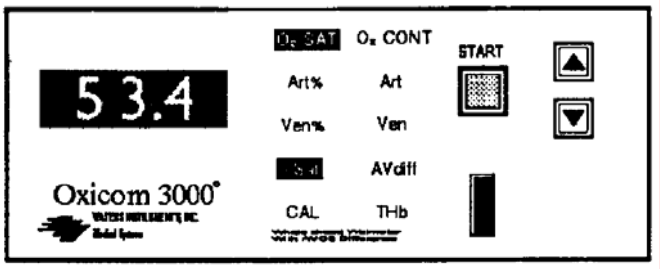


9. When "INS" is displayed, insert Low sample.

10. Display will show %Sat for Low sample. Enter the value of Low sample onto the worksheet.



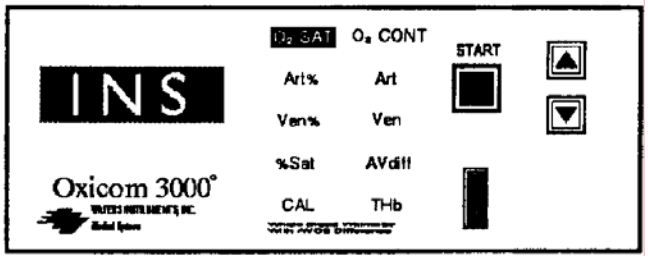
11. Remove Low sample, and the START button lights.



3.3 QUALITY CONTROL *Continued*

USER ACTION

12. Press the Start button. The Oxicom 3000 will still be in the operating mode, ready to accept blood samples.



When an error code is displayed refer to Section 5.5 Error Codes.

Upon repeating the test, if all samples indicate the correct %Sat, then the Oxicom 3000 is operating properly. However, if any of the QC samples displayed an incorrect value outside the ±7% range you should recalibrate the Oxicom 3000.

To measure O_2 saturation proceed to Section 3.4, Step 1.

To measure O2 content and calculate AVO_2 difference proceed to Section 3.5, Step 1.

Oxicom External Liquid Control QC Worksheet

Use this worksheet to record your weekly Quality Control readings

********** E X A M P L E ********** E X A M P L E **********

Oxicom 3000 S.N. 85786.251 Month: *January* Page 1 of 1

Last calibration: *October 19, 2005*

Sample:	HIGH	MID	LOW
Readings:	85.3	71.4	53.4
Range:			
From:	78.3	64.4	46.4
To: (±7%)	92.3	78.4	60.4

Location: *Cath Lab, E4*

The weekly readings should be within 7% Sat of the readings entered above.

Daily record:

Date	HIGH	MID	LOW	Corrective Action	Initial
11/2/2005	85.3	71.4	53.4	*New calibration - new references set*	dmo
11/9/2005	85.5	71.9	53.6	*none required*	dmo
. . .					
01/11/2006	85.4	75.1	60.8	*Due for calibration, talk to Jim at Bio-Med*	dmo

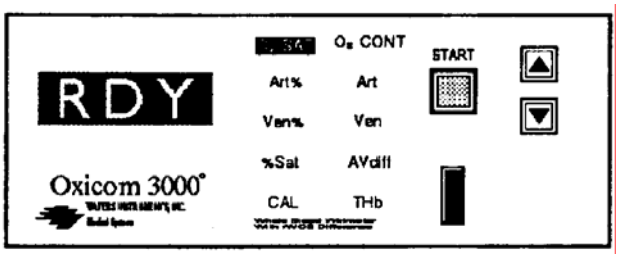
Worksheet Example

3.4 O_2 SATURATION MODE

USER ACTION

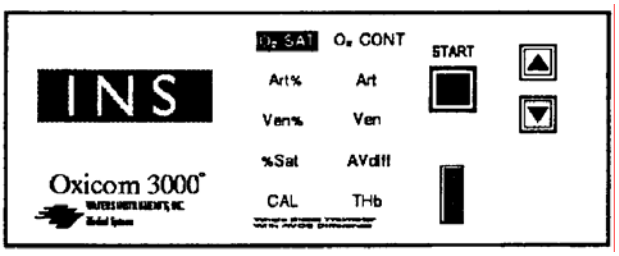
Refer to section 3.1 for proper techniques on handling blood and filling the Oxicom disposable cuvettes.

When warm-up and the Quality Control procedure has been completed, the Oxicom 3000 should be in the "RDY" state.



1. The O_2CONT/O_2SAT switch (Back Panel) should be in the O_2 SAT position.

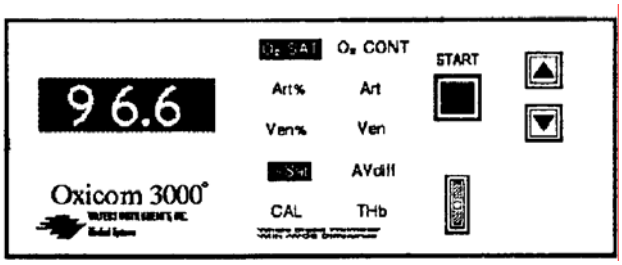
2. When the blood sample is ready and mixed properly, press the START button. Continue to mix the blood sample until "INS" appears on the display.



"INS" will appear in approximately 1-2 seconds.

3. Insert the blood-filled cuvette into the Sample Chamber with the bottom panel of the cuvette facing down.

DO NOT INJECT THE BLOOD INTO THE SAMPLE CHAMBER



Example reading 96.6

4. To measure additional samples repeat steps 2 and 3.

The Mode Display will indicate that the unit is in the O_2SAT mode and reading %Sat value of the sample.

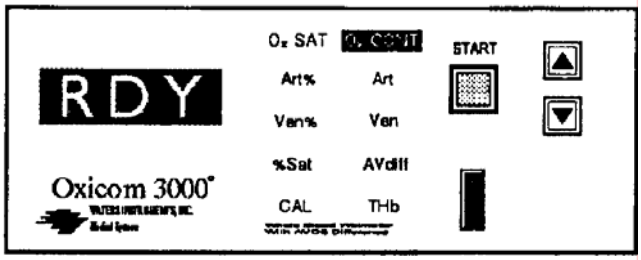
3.5 O_2 CONTENT MODE

USER ACTION

Refer to Section 3. 1 for proper techniques for handling blood and filling the Oxicom 3000 disposable cuvettes.

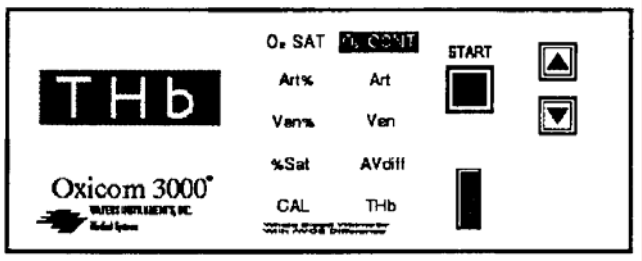
To measure O_2 content and calculate the AVO_2 difference you will need two blood samples, an Arterial and Venous.

When warm-up and the Quality Control procedure has been completed, the Oxicom 3000 should be in the "RDY" state.



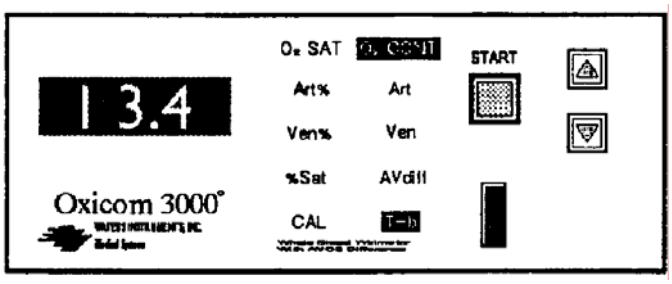
1. The O_2CONT/O_2SAT switch (Back Panel) should be in the O_2CONT position.

2. Press the START button.



Mode Display will indicate O_2CONT mode THb will appear on the display for a few seconds, followed by 13.4, or the last user entered Total Hemoglobin level.

3. To change the THb reading use the Arrow switches to the right of the START switch. To increase the reading press the UP arrow and to decrease the reading press the DOWN arrow.

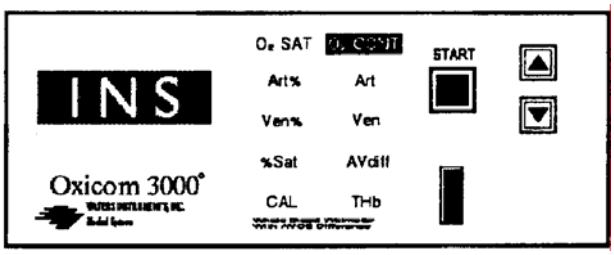


The Mode Display will indicate THb is being displayed.

3.5 O_2 CONTENT *Continued*

USER ACTION

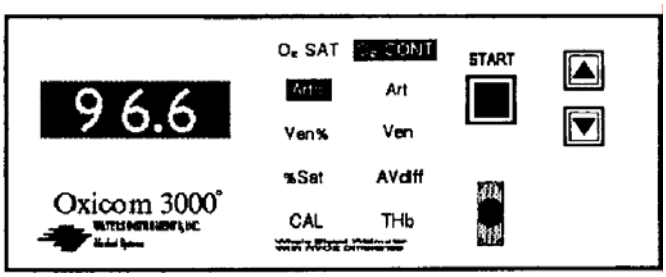
4. Push the START button to enter the THb value into the microprocessor.

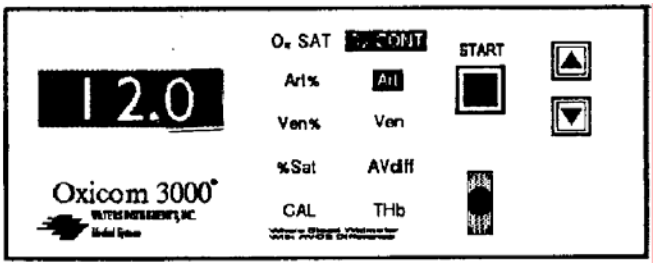


"INS" will appear on the display (approximately 1-2 seconds.) indicating the value was accepted and the Oxicom 3000 is ready to read the first sample.

5. Insert the first cuvette to be measured.

DO NOT PRESS START
Pressing START will abort the test.



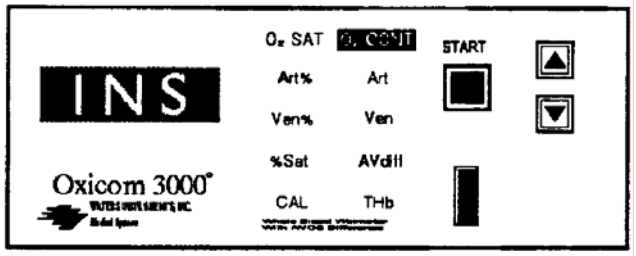


The oxygen saturation and content readings will alternately be displayed. The Mode Display will alternately indicate saturation (Art% or Ven%) or content (Art or Ven).

3.5 O_2 CONTENT *Continued*

USER ACTION

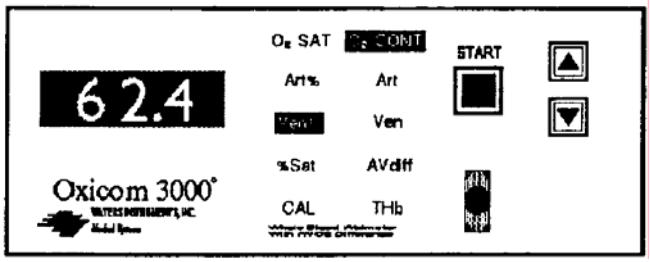
6. Remove the first sample.

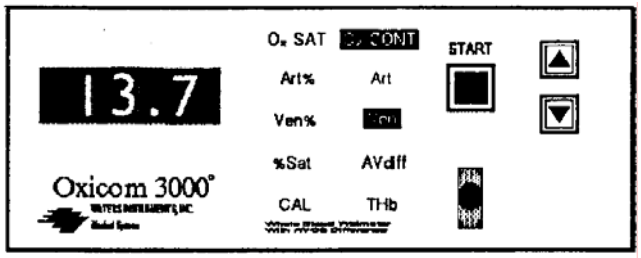


When the sample is removed "INS" is displayed.

7. Insert the second cuvette into the Sample Chamber.

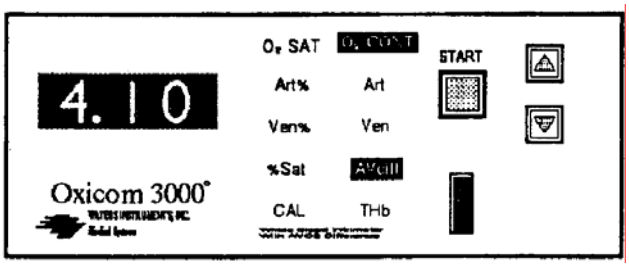
DO NOT PRESS START
Pressing START will abort the test.





The oxygen saturation and content will alternately be displayed. Again the Mode Display will indicate saturation or content reading.

8. Remove the second cuvette.



The display will read the Arterial - Venous difference.

3.5 O_2 CONTENT *Continued*

USER ACTION	Oxicom 3000 RESPONSE
9. To review the measured and calculated values, use the Arrow buttons to step through and read the values.	The display will read the following: AVdiff Ven (Venous Content) Ven% (Venous Oxygen Saturation) Art (Arterial Content) Art% (Arterial Oxygen Saturation) THb (Total Hemoglobin) The Mode Display will indicate the type of measurement being displayed on the Oxicom 3000 display.
10. To start another set of tests press the START button. Repeat steps 3 - 9.	

3.6 HEPARINIZE CUVETTES

The disposable cuvettes are not heparinized. Therefore, the user must take the necessary precautions to prevent the blood sample from clotting. If the oxygen saturation of the blood sample is going to be determined within ten minutes of withdrawal, heparin is not required.

1. Aspirate enough heparin into the syringe to completely coat the inside of the syringe.

2. Flush the heparin from the syringe. There will be enough heparin in the syringe to prevent the blood sample from clotting.

CAUTION

Due to the small volume of blood, care should be taken to evacuate all excess heparin from the syringe, as this will create discrepancies, just as with any blood analyzer.

3. Withdraw the blood sample into the syringe and remove any air that may have been pulled into the syringe.

4. Securely attach the cuvette and filter to the syringe. Slowly infuse the blood sample into the syringe. Tap the syringe while filling to remove any air bubbles.

5. Thoroughly mix the sample by rolling the syringe and cuvette between your hands in a horizontal position.

6. Insert cuvette into sample chamber as previously described.

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SECTION 4
CALIBRATION

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4.1 CALIBRATION THEORY

Your Oxicom 3000 was calibrated on human blood compared with a Co-Oximeter prior to shipment as shown on the calibration certificate which shipped with the Oxicom 3000. A blood gas analyzer should not be used because it measures PO_2 and uses this value to calculate fractional saturation.

To obtain the Oxicom 3000's rated accuracy the blood samples used should come from one donor, so that the hemoglobin level of both samples will be the same. The arterial sample should be between 90 and 99.9% and the venous sample should be between 60 and 72%. The carboxyhemoglobin level must not exceed 3%. The total hemoglobin level must be in the range of 12 g/dl ± 2 g/dl.

A Co-Oximeter (such as IL282/482 and OSM-3) uses several wavelengths to measure $\%O_2Hb$, %COHb, and %MetHb hemoglobin. This allows the Co-Oximeters to measure fractional oxygen saturation. The Oxicom 3000 is an oximeter which uses two wavelengths to determine the functional oxygen saturation. As COHb and MetHb become a larger percentage of the blood sample, the difference between functional and fractional saturation will increase. The functional saturation will be larger than the fractional saturation value.

For illustration purposes we will use the following data from a typical blood sample.

Hemoglobin Components: (Example Values)	g/dl	% by Wt.
1. Oxyhemoglobin (O_2Hb)	12.6	90.0
2. Carboxyhemoglobin (COHb)	0.42	3.0
3. Methemoglobin (MetHb)	0.21	1.5
4. Reduced Hemoglobin (RHb)	0.77	5.5
5. Total Hemoglobin (THb)	14.0	100.0

FRACTIONAL SATURATION
(Calculated by the Co-Oximeter)
Fractional saturation is the amount of oxygenated hemoglobin as it relates to all hemoglobin represented within a blood sample. This value is typically expressed as a percentage.

Fractional Saturation:

A)

$$\%SAT = \frac{\%O_2Hb}{\%O_2Hb + \%COHb + \%MetHb + \%RHb} x100$$

$$\%SAT = \frac{90.0}{90.0 + 3.0 + 1.5 + 5.5} x100 = 90.0\%$$

FUNCTIONAL SATURATION
(Calculated by the Oxicom 3000)
Functional saturation is the amount of oxygenated hemoglobin as it relates to the total amount of hemoglobin available for oxygenation. This is typically expressed as a percentage.

Functional Saturation:

B) $$\%SAT = \frac{\%O_2Hb}{\%O_2Hb + \%RHb} x100$$

$$\%SAT = \frac{90.0}{90.0 + 5.5} x100 = 94.24\%$$

Functional saturation may be calculated using the following equation and hemoglobin levels measured by a Co-Oximeter. Equation B and C give the same results.

C) $$\%SO_2M = \frac{\%O_2Hb}{100 - \%COHb - \%MetHb} x100$$

$$\%SO_2M = \frac{90.0}{100 - 3.0 - 1.5} x100 = 94.24\%$$

4.2 BLOOD SAMPLE PREPARATION

Supplies and Equipment Required:

Co-Oximeter; Such as IL282 or 482, or Radiometer OSM-3 or Corning 2500 or comparable units
DC-80 Disposable Cuvettes, 2 each with white porous filters.
Syringe 5 cc- heparinized 2 each
Syringe 10 cc heparinized (optional)
Needle - 16 gauge
Syringe caps - 2 each
Paper towels or tissues
Oxicom 3000 Calibration Worksheet
Oxicom QC Worksheet

OVERVIEW OF THE CALIBRATION PROCEDURE

Obtain blood samples:

Method A is to obtain 6 ml of venous blood and divide the sample. See Section 4.2.1.

Method B is to obtain 3 ml of venous and 3 ml of arterial blood. See Section 4.2.2.

Determine the functional saturation value of the two samples. See Section 4.3.

Calibrate the Oxicom 3000. See Section 4.4, Steps 1-8.

Measure and store the optical densities of the three Quality Control filters. Section 4.4, Steps 9-16.

SUGGESTIONS:

The hemoglobin value must be between 10 to 14 gm/dl.

The carboxyhemoglobin should be less than 3%.

Take the Oxicom 3000 to the Co-Oximeter's location.

Mix the blood samples prior to inserting them into the sample chamber.

4.2.1 VENOUS BLOOD SAMPLE PREPARATION

The following steps are to be used when only a venous sample is available. Proceed to step 4.2.2 if you have an arterial and venous sample.

1. Withdraw 6 ml of venous blood into a 10 ml syringe. The venous sample should have a saturation reading of 60-72 %O_2 saturation. This should be verified with a co-oximeter.

2. Attach a 16 gauge needle to the second 10 cc syringe and aspirate 1.5 to 2 ml of blood from the venous supply in step one above. This will become the arterial (high) O_2 sample.

CAUTION

Care should be taken not to create an air space in the venous sample. This can be done by aspirating the air from the venous supply at the same time you withdraw blood into the high sample syringe.

3. Immediately cap the low sample, so that the O_2 saturation does not increase, and set it aside.

4. Aspirate as much room air into the arterial, high sample syringe as possible. Cap the syringe and vigorously roll the syringe in a horizontal position for two minutes. You may have to evacuate the air and draw in additional room air. This will increase the O_2 saturation .

4.2.1 VENOUS BLOOD SAMPLE PREPARATION *Continued*

5 Mount a disposable cuvette on the high sample syringe. Do not install the white filter.

6 Infuse blood from the high sample into the cuvette. Avoid any air bubbles that may adhere to the cuvette, by gently tapping the edge.

7 Measure the O2 saturation of the high sample using your co-oximeter. It is important that the level of blood in the cuvette be maintained. Infuse blood into the cuvette as it is being withdrawn. The high sample's fractional saturation should be greater than 90%.

8 If your co-oximeter measures fractional O2 saturation only, then be sure to note the %O2, %COHb and %MetHb readings. These readings will be needed to calculate the functional saturation value in step 11 below.

9 Upon completion of measuring the high sample, expel 0.1 cc of blood onto a paper towel (waste blood). Pull the blood back into the cuvette enough to void the cuvette tip of any blood.

Install the white filter into the tip of the cuvette and fill the cuvette to the filter.

10 Repeat steps 7 through 9 with the venous sample. The venous sample should have a functional saturation value of 60 to 72 %SAT

11 If you use an IL 482 CO-Oximeter, it will calculate the functional saturation value. However if your co-oximeter measures fractional saturation (%O_2Hb) only, then you will have to calculate functional saturation using the following formula.

$$\%SO_2M = \frac{\%O_2Hb}{100 - \%COHb - \%MetHb} x100$$

%SO_2M:	% Saturation O_2 Measured (Functional Saturation)
%O_2Hb:	% Oxygenated Hb (Fractional Saturation)
%COHb:	% Carboxyhemoglobin
%MetHb:	% Methemoglobin

NOTE

If %COHb or %MetHb are negative, recheck your co-oximeter.

4.2.2 ARTERIAL & VENOUS BLOOD PREPARATION

1. Withdraw 3 ml of arterial and venous blood into each of the 5 ml syringes. The venous sample's value should be between 60-72 %SAT and the arterial should be greater than 90%.

CAUTION

Care should be taken not to create an air space in the venous sample. This can be done by aspirating the air from the venous supply at the same time you withdraw blood into the high sample syringe.

2. Mount a disposable cuvette on the high sample syringe. Do not install the white filter. Avoid any air bubbles that may adhere to the cuvette by gently tapping the edge.

3. Measure the O_2 saturation of the arterial (high) sample using your co-oximeter. It is important that the level of blood in the cuvette be maintained. Infuse blood into the cuvette as it is being withdrawn. The high sample's functional saturation should be greater than 90%.

4. Upon completion of measuring the high sample, expel 0.1 cc of blood onto a paper towel (waste blood). Pull the blood back into the cuvette enough to void the cuvette tip of any blood. Install the white filter into the tip of the cuvette and fill the cuvette to the filter.

5. If your co-oximeter measures fractional O_2 saturation then be sure to note the $\%O_2$, %COHb and %MetHb readings. These will be needed to calculate the functional saturation value in step 7 below.

6. Repeat steps 2 through 5 with the venous sample.

7. If you use an IL 482 or similar CO-Oximeter, it will calculate the functional saturation value. However if your CO-Oximeter measures fractional saturation ($\%SO_2M$) only, then you will have to calculate functional saturation using the following formula.

$$\%SO_2M = \frac{\%O_2Hb}{100 - \%COHb - \%MetHb} x100$$

$\%SO_2M$:	% Saturation O_2 Measured (Functional Saturation)
$\%O_2Hb$:	% Oxygenated Hb (Fractional Saturation)
%COHb:	% Carboxyhemoglobin
%MetHb:	% Methemoglobin

NOTE

If %COHb or %MetHb are negative, recheck your co-oximeter.

4.3 DETERMINE FUNCTIONAL OXYGEN SATURATION

It is recommended that the Oxicom 3000 be moved to the CO-Oximeter.

Upon receipt of the two blood samples evacuate any air bubbles that may be present in the individual syringes.

Most CO-Oximeters measure fractional oxygen saturation. In order to calibrate the Oxicom 3000, convert the fractional saturation to functional saturation. Use the calibration worksheet, page 74, to calculate the functional saturation.

The formula to convert fractional to functional saturation is as follows:

$$FunctionalSat = \frac{\%O_2Hb}{100 - \%COHb - \%MetHb} x100$$

The following instructions apply to both the arterial and venous samples

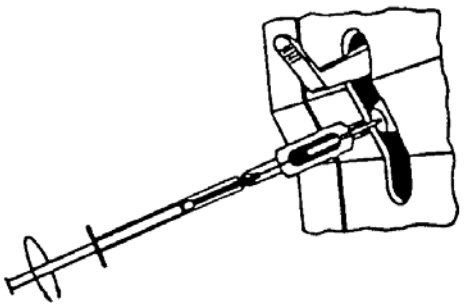
1. Evacuate any air bubbles that may remain in the two blood samples.

2. Mount a disposable cuvette, without the white filter, to the syringe tip.

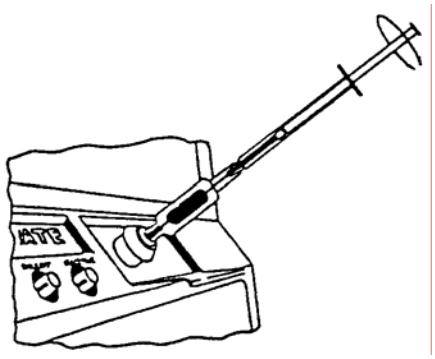
3. Carefully infuse the blood sample into the cuvette. To minimize air bubbles, which will change the saturation value, the cuvette should be pointed up and the blood should be infused slowly. Hint: Tap the cuvette to knock any bubbles loose.

4. Withdraw or inject the sample into the co-oximeter. If your co-oximeter withdraws blood, be sure to keep the cuvette full. This can be done by gently infusing blood into the cuvette as it is being withdrawn.

5. Note the fractional saturation, COHb and MetHb values measured by the co-oximeter. Enter them into the formula above and calculate the functional saturation of the sample.



IL Co-Oximeter
Figure 4.1



OSM3 Oximeter
Figure 4.2

4.4 CALIBRATION

The sample chamber must be inspected and cleaned prior to calibrating the Oxicom 3000.

NOTE

The rated accuracy is achieved only after the 15 minute warm-up.

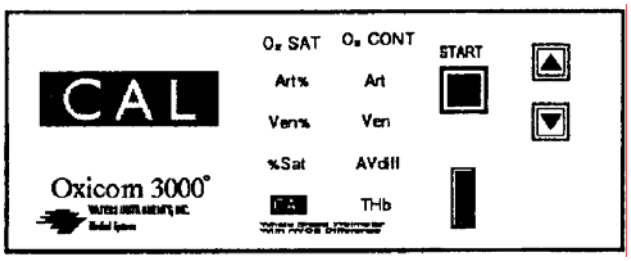
USER ACTION

1. To calibrate, the Oxicom 3000 must be placed in the calibration mode.

   Turn the POWER switch Off.

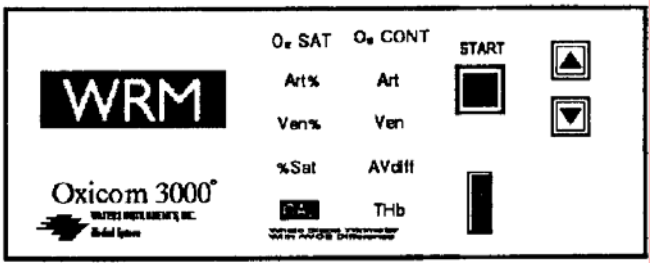
   Press and hold the START button. Turn the POWER switch to ON. When "CAL" appears on the display release the START button.

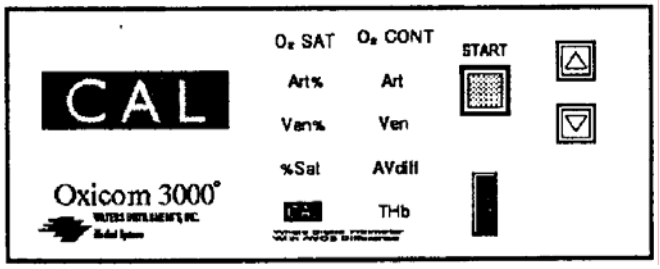
Oxicom 3000 RESPONSE



Mode Display performs a system check.

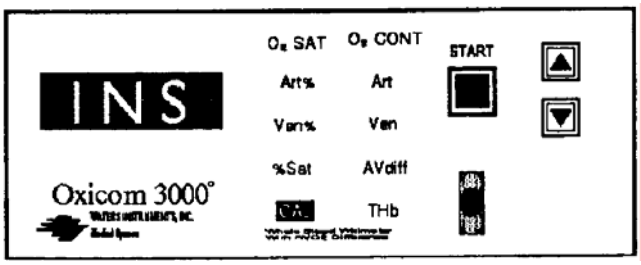
2. If the Oxicom 3000 has been on for a minimum of 15 minutes you can bypass the additional 15 minutes warm-up by pressing the START button again. If the unit has not been on, wait for the Display to read "CAL".





Mode Display indicates CAL

3. Press and release START.

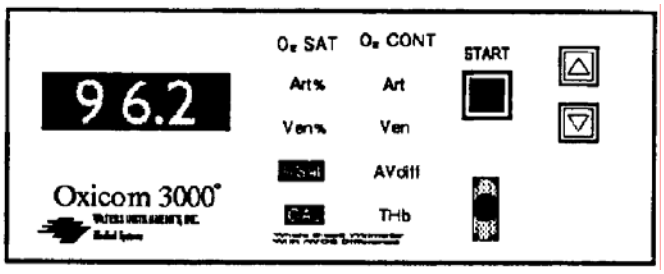


4.4 CALIBRATION *continued*

USER ACTION

Oxicom 3000 RESPONSE

4. When "INS" is displayed insert the arterial sample.

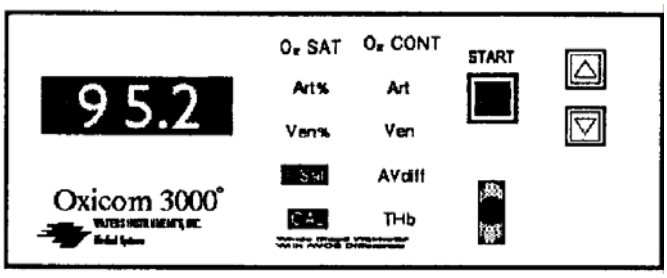


Example reading 96.2

CAUTION

If an error code is displayed upon inserting the blood sample, check the sample chamber for blood or foreign material Clean the sample chamber per Section 5.3. If the error code remains after cleaning, refer to Section 5.5, Error Codes.

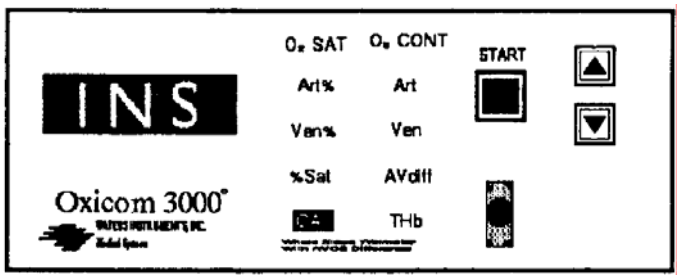
5. Leaving the cuvette in the sample chamber, use either the up or down arrows to increase or decrease the displayed value calculated by the co-oximeter, or in this example 95.2



Example, display reset to 95.2
Mode Display: CAL and %Sat are on..

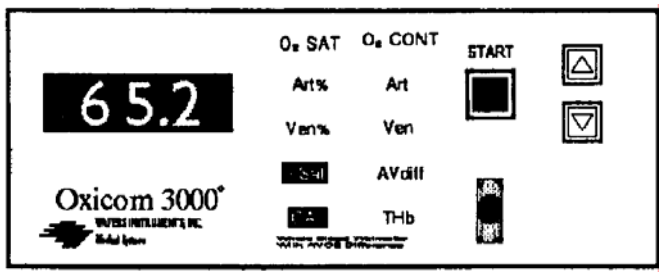
6. Remove the first blood sample.

7. When "INS" is displayed insert the second or venous sample.



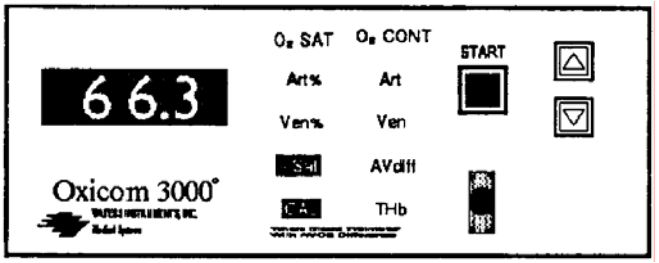
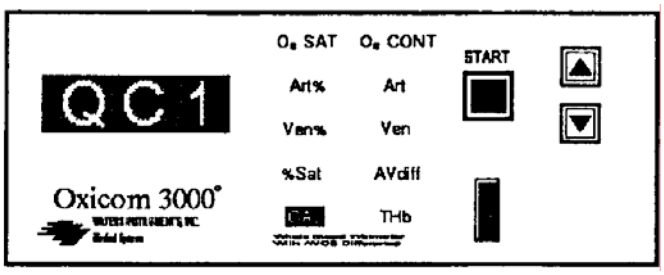
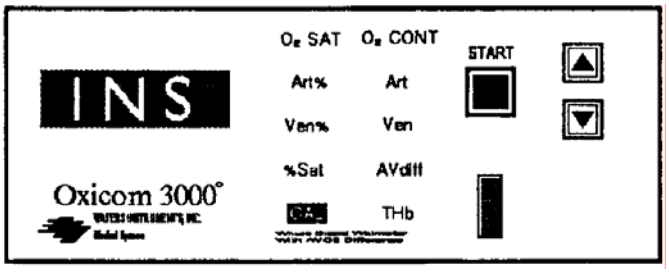
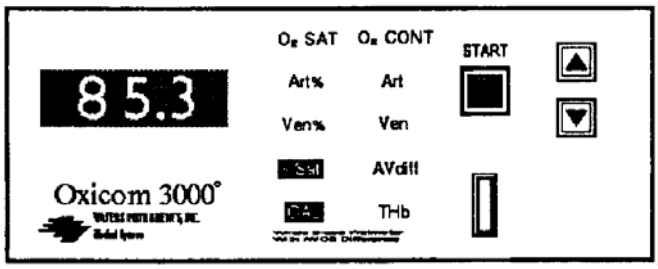
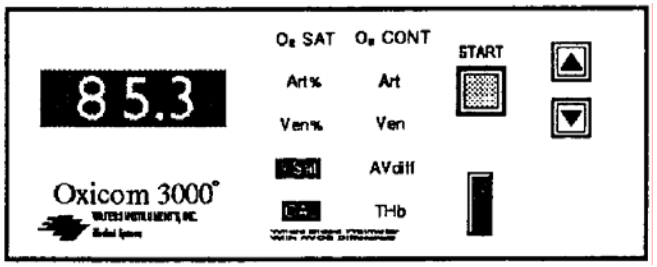
CAUTION

If an error code is displayed upon inserting the blood sample, check the sample chamber for blood or foreign material. Clean the sample chamber per Section 5.3. If the error code remains after cleaning, refer to Section 5.5, Error Codes.

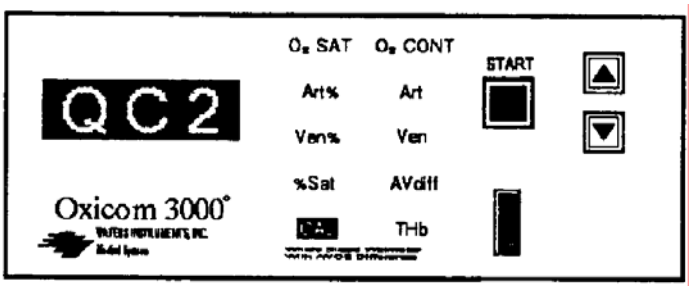
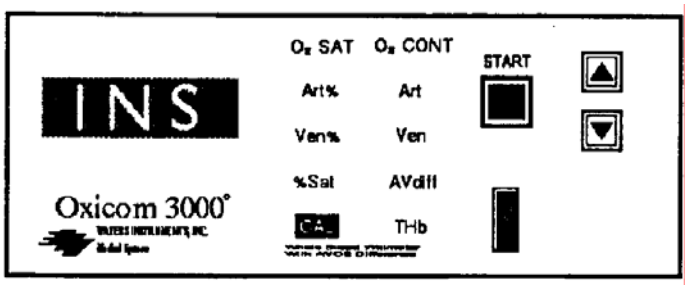
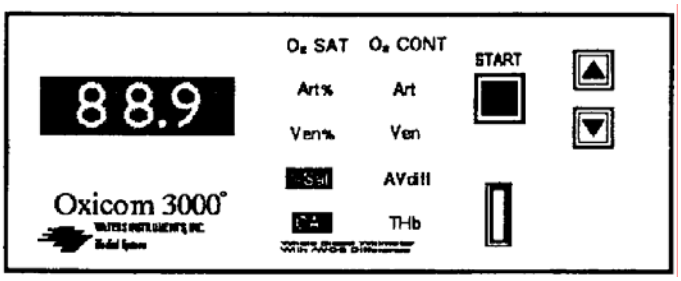
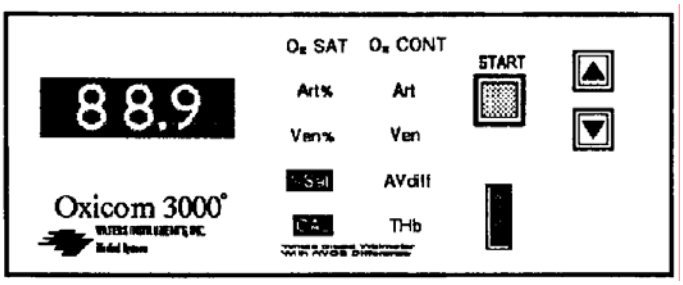
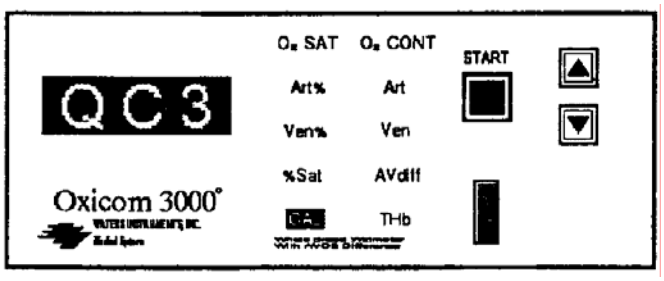


Example reading 65.2
Mode Display: CAL and %Sat are on.

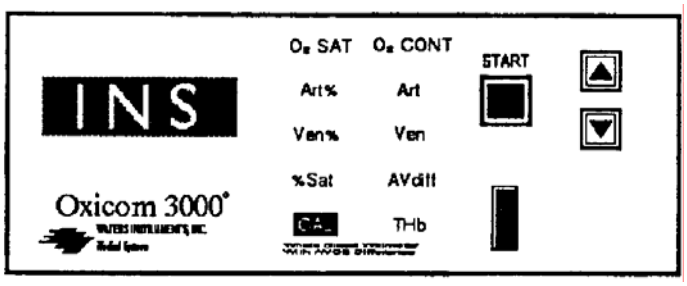
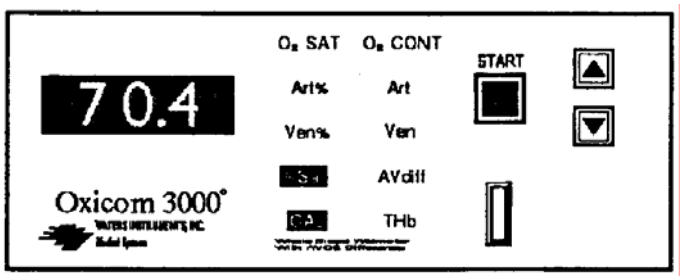
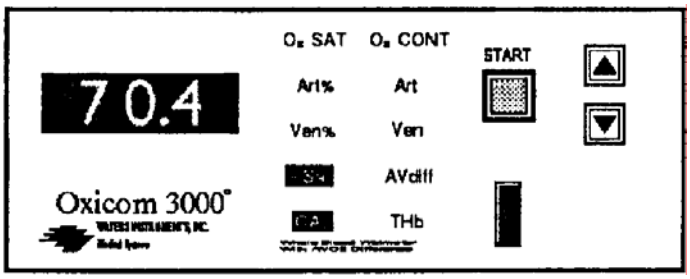
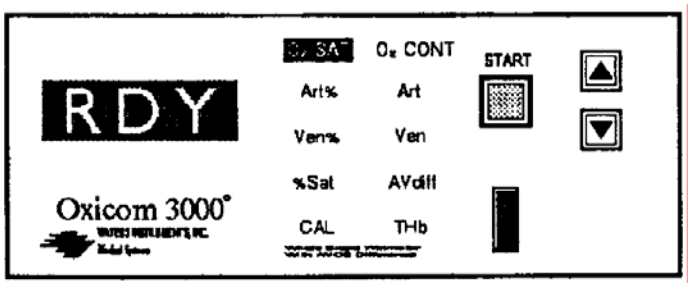
4.4 CALIBRATION *continued*

USER ACTION	Oxicom 3000 RESPONSE
8. Use the Arrow switches to adjust the display to the calculated value in Section 4.3.	
9. When the Low blood sample has been measured and any adjustments made, upon removal of the blood sample "QC1" will be displayed for a moment. *NOTE* *It may take one to two minutes before the Oxicom 3000 has stored the new settings and "QCI" is seen on the display.*	 "QC1" momentarily displayed.
NOTE *The Quality Control Filters must be inserted in sequence; QCI, QC2, & QC3.* 10. Wait for "INS" to be displayed, then insert the QCI filter. The display's decimal points will alternate position, indicating that the QC1 data is being measured and stored into memory. 11. Enter the reading for QC1 onto the Quality Control Worksheet, below QC1 and opposite Readings. 12. Remove QC1.	   The START button lights.

4.4 CALIBRATION *continued*

USER ACTION	Oxicom 3000 RESPONSE
13. Press the Start button and "QC2"will be displayed for a moment.	
14. When "INS" is displayed, insert QC2.	
15. The display will show the %Sat reading for QC2. Enter the value onto the Quality Control Worksheet, below QC2 and opposite Readings.	
16. Remove QC2, and the Start button lights.	
17. Press the Start button and "QC3" will be displayed for a moment.	 "QC3" momentarily displayed.

4.4 CALIBRATION *continued*

USER ACTION	Oxicom 3000 RESPONSE
18. When "INS" is displayed, insert QC3.	
19. Display will show %Sat for QC3. Enter the value of QC3 onto the Quality Control Worksheet, below QC3 and opposite Readings.	
20. Remove QC3, and the Start button lights.	
21. Press the Start button and "RDY" will be displayed. The Start button will be on.	
	When reprogramming has been completed the display will ready "RDY".
22. Press the Start button. Oxicom 3000 will be in the operating mode, ready to accept samples.	

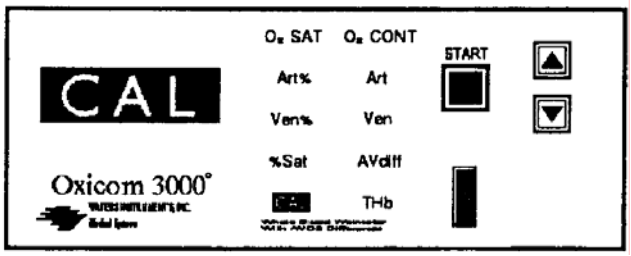
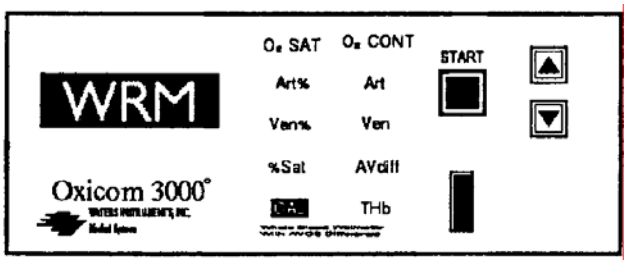
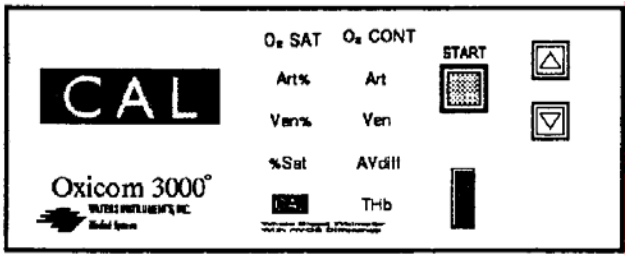
4.5 OXYGEN CONTENT CAPACITY ADJUSTMENT

To calculate AVO_2 content, the Oxicom 3000 measures O_2 saturation, multiples that value by the patient's entered hemoglobin value and the oxygen content capacity. Since a gram of hemoglobin can carry 1.34 ml of oxygen, to calculate the oxygen content of blood, the Oxicom 3000 uses the formula:

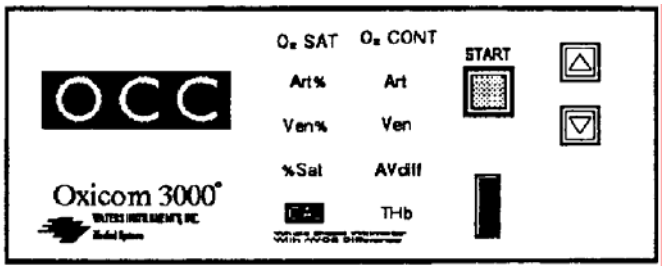
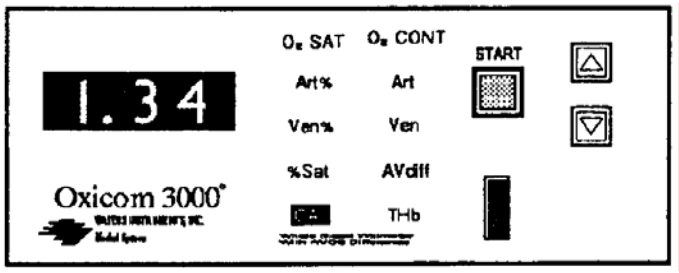
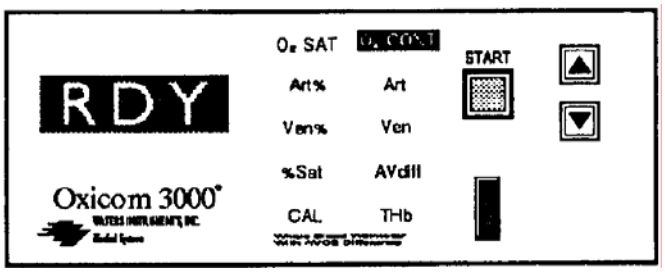
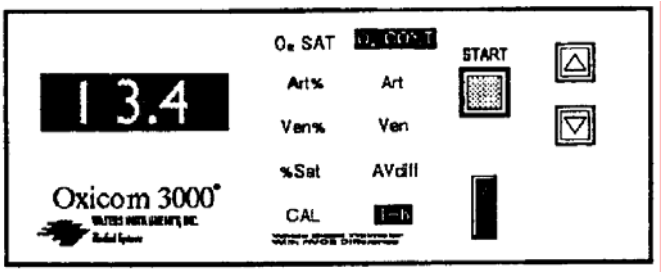
Volume $\%O_2$ = 1.34 ml x THb x $\%O_2Hb$

The Oxicom 3000 utilizes the oxygen capacity value of 1.34 ml/g. The following procedure allows you to change the default value to either 1.36 or 1.39.

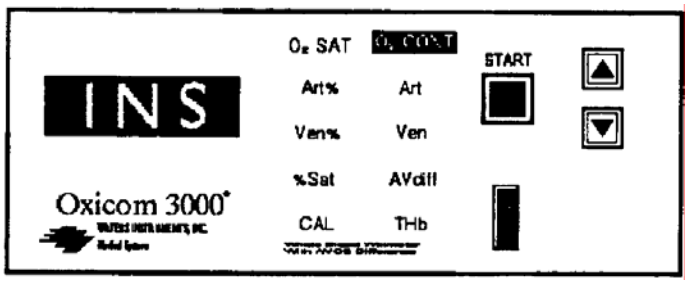
Turn on the Oxicom 3000 while it is in O_2CONT mode. The default total hemoglobin value displayed is ten times the Oxygen Content Capacity (OCC).

USER ACTION	Oxicom 3000 RESPONSE
1. Place the Oxicom 3000 in the O_2CONT mode.	
2. With the unit off press and hold in the START button.	
3. Turn the POWER switch On.	The display performs self test.
	
	"WRM" will be displayed for 15 minutes.
4. If the unit has been on for 15 minutes, prior to placing it in the "CAL" mode, press the START button.	
	Mode display indicates CAL mode.

4.5 OXYGEN CONTENT CAPACITY ADJUSTMENT *continued*

USER ACTION	Oxicom 3000 RESPONSE
5. To place the Oxicom 3000 in the Oxygen Content Capacity (OCC) constant mode press one of the Arrow buttons.	
6. Press START to view the current OCC.	 Display will read 1.34, 1.36 or 1.39.
7. To change the OCC press either Arrow button to select 1.34, 1.36 or 1.39. 8. To save the new value press the START button.	 "RDY" will be displayed.
9. Press START. The display should indicate "THb" then change to a number equal to 10 times the OCC entered.	 Mode display indicates O_2CONT and THb.

4.5 OXYGEN CONTENT CAPACITY ADJUSTMENT *continued*

USER ACTION	Oxicom 3000 RESPONSE
10. Press START to measure samples. The Oxicom 3000 is now ready to measure arterial and venous samples and calculate the AVO_2 difference. Return to Section 3.5 O_2 Content Mode.	

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SECTION 5
MAINTENANCE

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5.1 MAINTENANCE SCHEDULE

DAILY:

The Oxicom 3000 should be checked daily with the Quality Control (QC) filters. Enter the filter reading onto the Oxicom QC Worksheet, page 72 in the Appendix.

WEEKLY:

The sample chamber should be inspected for dust, blood and any foreign material. The Oxicom 3000 should be checked weekly with the Liquid Control (QC) samples. Enter the sample reading onto the Oxicom QC Worksheet, page 73 in the Appendix.

QUARTERLY:

The accuracy of the Oxicom 3000 should be verified every three months. To check the accuracy of the Oxicom 3000, obtain 2 to 5 mL of blood, preferably a venous sample in the 60% to 72% range. Measure the saturation with a co-oximeter and calculate the functional saturation. Compare the functional saturation value of the co-oximeter to the value measured by the Oxicom 3000. If the Oxicom 3000 is not within 3% of the calculated value the Oxicom 3000 should be re-calibrated. For example if the calculated value is 72%, the Oxicom 3000 should read between 69% to 75%.

SEMIANNUALLY:

The calibration should be confirmed twice a year following Section 4 Calibration in this manual.

5.2 QUALITY CONTROL FILTERS - CLEANING

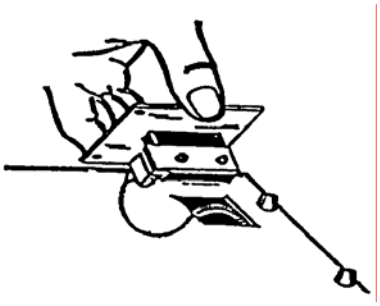
To clean the Quality Control Filters use a glass cleaner and a lint free cloth. Be sure the filters are dry prior to inserting after cleaning

5.3 SAMPLE CHAMBER CLEANING

If blood is accidentally infused into the sample chamber, the sample chamber must be removed from the Oxicom 3000 and cleaned. You will need a cotton swab and alcohol to clean the sample chamber. To remove the sample chamber follow these instructions.

1. Turn the power off. Turn the Oxicom 3000 up side down and remove the four screws located on the outside edge of the late. Do not remove the two remaining screws.

2. Carefully lift the plate and remove the detector half of the sample chamber.



3. Use an alcohol swab to clean the detector and fiber optic cable tip. Do not allow the components to become saturated with alcohol.

4. To clean the inside half of the sample chamber reach in through the opening normally covered by the plate. Use a suitable light and direct it through the front panel. Both sections should be cleaned and wiped dry.

5. Reassemble the unit and check the with the Quality Control (QC) filters.

5.4 FACTORY DEFAULT SETTINGS

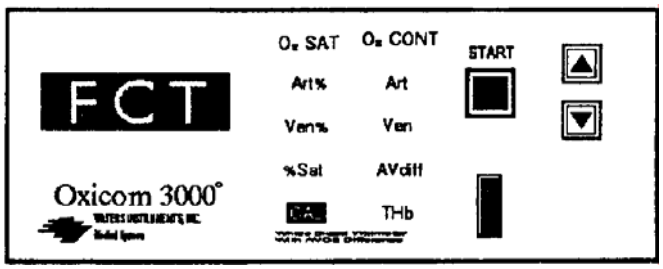
This procedure allows the user to recalibrate the Oxicom 3000 utilizing the original factory settings as a starting point. If cleaning the sample chamber does not eliminate the error code the unit must be reset and re-calibrated.

USER ACTION

Oxicom 3000 RESPONSE

The Sample Chamber must be clean.

1. To enter the factory calibration mode:
   The O_2CONT/O_2SAT switch should be in the O_2SAT position.
   Remove the QC filter.
   With the unit turned Off
   Press and hold both Arrow buttons in.
   Turn the POWER switch to On. Release the Arrow buttons when "FCT" is displayed.



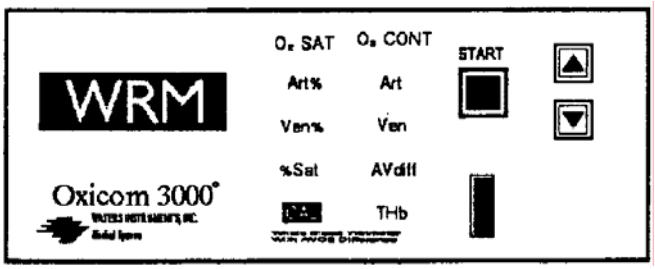
The Oxicom 3000 performs a display and indicator check.

CAUTION

An arterial and venous blood sample must be used to calibrate the Oxicom 3000. The samples must be fresh and mixed completely, review Section 4.2.

The factory default settings will not provide an accurate calibration. They are intended to be used only as a starting point for a normal calibration, see Section 4.4.

2. If unit has been on for more than 15 minutes, bypass the warm-up by pressing START.



5.4 FACTORY DEFAULT SETTINGS

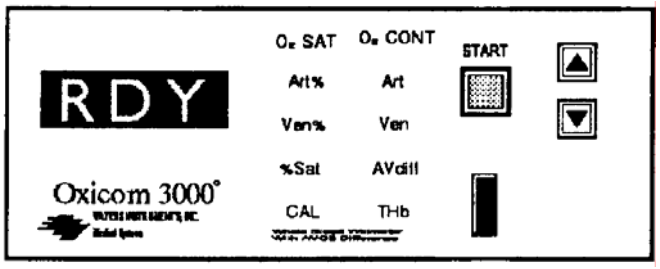
Continued

USER ACTION

3. The Arrow buttons will switch the Oxicom 3000 from ready ("RDY") or calibrate ("CAL") mode.

To select the operate mode, press START when "RDY" is displayed.

Oxicom 3000 RESPONSE

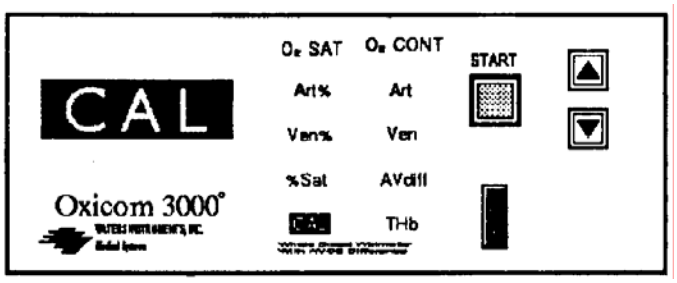


"RDY" is displayed.

or

To select the calibration mode, press START when "CAL" is displayed.

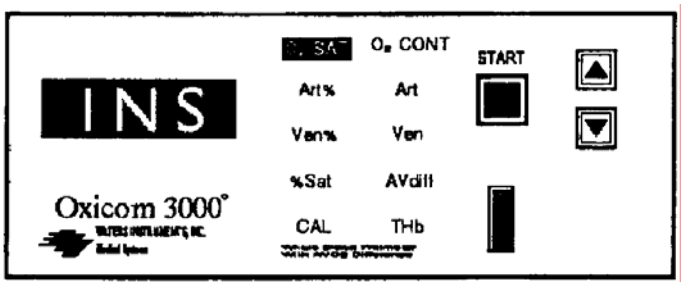
NOTE.- If the wrong mode is selected, turn unit off and start over



"CAL" is displayed.

4. If you wish to continue the calibration procedure go to Section 4.4.

5. When "RDY" is selected the current default settings are used and the Oxicom 3000 will display "INS".



CAUTION

The factory default settings will not provide an accurate calibration. They are intended to be used only as a starting point for a normal calibration. Refer to Section 4.4 for calibration instructions.

5.5 ERROR CODES

MESSAGE	CAUSE	CORRECTIVE ACTION
CLN	Blood or foreign material in the sample chamber.	Clean the sample chamber.
RMV	Inserting the sample before "INS" is displayed.	Remove the sample. Wait for "INS" to appear, then insert the sample.
ERI - ER5	Measuring a blood sample that has separated. Blood separation can be caused by: 1. Blood diluted by heparin or saline. 2. Blood samples more than 10 minutes old. 3. The cuvette was laid on edge, the clear sampling area should be laid face down.	Mix the samples by rolling the syringe between your hands. Hold the syringe horizontally. If enough blood remains in the syringe, discard the cuvette and refill a second cuvette.
	Streaks in the blood sample.	Discard the sample and obtain a second sample.
	Blood in the sample chamber.	Clean the sample chamber
	The Oxicom 3000 may have been calibrated on a bad blood sample.	Recalibrate the unit.
ER6	Both samples measure within 2% of each other.	Retest the samples, making sure both samples are measured.
ER7 or ER8	The internal voltage references are out of tolerance.	Unit is operating beyond its temperature, humidity limits or an electronic failure mis-adjustment has occurred.

5.5 **ERROR CODES** *continued*

MESSAGE	CAUSE	CORRECTIVE ACTION
ER9	The ratio of the optical densities (ODR/ODIR) is outside the range of 0.5 to 2.0.	Corrective action is the same as for codes ERI - ER5 above.
ERa	The Red LED is out of tolerance or not operating.	Repair or troubleshoot circuit.
ERb	The IR LED is out of tolerance or not operating.	Repair or troubleshoot circuit.
ERc	During calibration a high sample was measured and the user entered a low value. Then the low sample was measured and the user entered a high value.	Press the Start button to clear the error, then repeat the calibration procedure, Section 4.4, Step 3.
ERd	The factors derived during calibration are out of range.	This is caused by using bad blood samples or entering the wrong target values. Obtain new blood samples and recalibrate the Oxicom 3000.
ERe	Optical Density, measured by the Oxicom 3000 is out of tolerance.	Repeat QC test, be sure to insert QC filters in the correct sequence. Clean the QC filters. Clean sample chamber and repeat QC test. Check the calibration. Recalibrate the Oxicom.

5.5 ERROR CODES *continued*

MESSAGE	CAUSE	CORRECTIVE ACTION
*	An asterisk showing in the display's left segment. This is caused by the measured value exceeding 99.9% saturation.	The functional saturation must be between 60-72% venous and 90-99.9% arterial The THb level of the sample must be 10-14 gm/dl. The %COHb, carboxyhemoglobin must be less than 3%.

5.6 ERRONEOUS READINGS

DUE TO ...	CHECK THE FOLLOWING:
Warm-up	The rated accuracy is achieved only after the 15 minute warm-up. Allow the Oxicom 3000 to warm-up. The Oxicom 3000 will display "RDY" or “CAL" (in the calibration mode) when it is fully warmed up. The Oxicom 3000 is designed to be used in an environment of 65-85 degrees F.
Cuvette, sample preparation and handling	Do not touch or contaminate the sampling area of the cuvette (clear area) with blood or foreign substances. Always handle the cuvette along the edge. Inspect the cuvette(s) for cleanliness prior to injecting the blood. Blood, powder from sterile gloves, or any foreign material on the cuvette's external surface, may affect the measurement. Care should be taken not to create an air space within the blood sample. If micro bubbles are present, the oxygen saturation of the sample will rise 1-2%. Be sure the blood sample is mixed, of uniform consistency and free of bubbles. Immediately cap the low sample cuvette with a white filter. Always point the syringe and cuvette up to prevent oxygenation of the blood sample. Do not reuse cuvettes or white filters. If the cuvettes are reused an erroneous reading may result due to any obstruction of the optical path. Reusing the white filters may allow oxygen contamination of the blood sample which will increase the percent saturation and content readings. Do not insert the sample before "INS" is displayed. Remove the sample if "RMV" is displayed. Wait for "INS" to appear, then insert the cuvette. Do not remove the sample before a reading is completed. Always insert the cuvette with the bottom panel facing down for more repeatable readings.

5.6 ERRONEOUS READINGS *Continued*

DUE TO ...	CHECK THE FOLLOWING:
Cuvette, sample preparation and handling *cont.*	Do Not measure a blood sample that has separated. Blood separation can be caused by: 1. Blood diluted by heparin or saline. 2. Blood samples more than 10 minutes old. 3. The cuvette was laid on edge. If the sample has streaks or other abnormalities in it, try to obtain a new sample, as they will affect the readings. Heparin and saline dilute and lower the hemoglobin level of the sample. Prior to withdrawing a sample of blood from any arterial line, the operator should aspirate 3-5 cc of blood from the line to remove any residual heparin or saline. The disposable Oxicom 3000 cuvette are not heparinized. Therefore, the user must take the necessary precautions to prevent the blood sample from clotting. However, if the sample is going to be used within ten minutes of withdrawing, heparin is not required. To calibrate the Oxicom 3000, the blood should be drawn into a properly heparinized syringe. The presence of dyes will affect oxygen saturation readings. lndocyanine (Cardio) Green, Evans Blue and Methylene Blue absorb light at the same frequencies as blood. Be sure that blood samples are taken prior to injecting dye into the patient. Do not inject blood into the sample chamber. The chamber must be cleaned and the accuracy must be checked. The samples used to calibrate the Oxicom 3000 must meet the following parameters: 1. The arterial or high sample should read between 90-99.9% saturation. 2. The venous or low sample should read between 60-72% 3. The THb value must be between 10-14 gm/dl. 4. The carboxyhemoglobin (%COHb) must not exceed 3%.
Display malfunction	The display will perform a system check each time the unit is turned on. All light segments will cycle on and off during this test.

5.6 ERRONEOUS READINGS *Continued*

DUE TO ...	CHECK THE FOLLOWING:
O_2SAT/O_2CONT Mode Switch	If the mode switch is changed during a test, the test will be aborted and you will have to restart your tests. Remember to make sure the samples are well mixed prior to repeating the test.
Quality Control Filters & Liquid Control Samples	Do not insert the Quality Control (QC) filters/samples until "INS" is displayed on the Oxicom 3000 display Failure to keep the QC filters clean may cause a shift in readings. Clean the Quality Control filters with alcohol and retest. Whenever the unit is re-calibrated the QC filter readings will have to be stored into the memory section of the microprocessor (see Section 4.4). Liquid controls can be improperly mixed causing an incorrect sample concentration or settling within the cuvette giving a shift in readings. Blood or other substances in the sample chamber may cause a shift in readings. See Section 5.2 for instructions on how to clean the sample chamber.

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SECTION 6
APPENDIX

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Oxicom 3000
SPECIFICATIONS

Specified Accuracy Range:

Oxygen Saturation	45% to 99%
Total Hemoglobin	8 to 18 gm/dl
pH	7.25 to 7.55
Saturation Accuracy	± 0.6 %SAT
Content Accuracy	± 1 Digit
Repeatability	± 0.5 %SAT

Content Mode Variables: (User entered)

Total Hemoglobin	4 - 24 gm/dl
Oxygen Carrying Capacity	1.34, 1.36, 1.39

Sample:

Type	Whole Blood
Size	0.5 ml

Operating Environment:

Temperature	65 - 85 °F (18.3 - 29.4 °C)
Humidity	0 to 95% (Non-condensing)
Power	100 to 240 VAC
Frequency	50 to 60 Hz

Physical:

Size (inches)	9.75"W x 3.75"H x 9"D
(cm)	24.8 W x 9.5 H x 23 D
Weight	3.75 lb. (1.7 kg)
Shipping Weight	8 lb. (3.64 kg) (approx.)

Approvals

Underwriters Laboratories	UL-61010A-1,
International Certifications	EN55011 Class A and
	EN61000-3 and
	EN61326-1:1997 Amend A1:1998

Measurement:

As Calibrated Clinical Accuracy

After completing the calibration procedure, the Oxicom 3000 will repeatedly measure the calibration samples with the indicated accuracy.

Anticipated Clinical Accuracy:

The Oxicom 3000 will measure randomly-selected samples with the following Functional Oxygen Saturation (FOS) accuracy. FOS is the percent of O_2Hb as it relates to the total hemoglobin available for oxygenation.

Oxygen Saturation	Saturation Accuracy	Content Accuracy	Repeatability
95 - 100%	±1% SAT	±1digit	0.5% SAT
85 - 94.99%	±2% SAT		
70 - 84.99%	±2.5 % SAT		

Accuracy:

After calibration 68% (one standard deviation) of all test data lies within the specified limits of the above stated accuracy's. The content values displayed are calculated from the oxygen saturation, the user entered THb level and the oxygen carrying capacity. Therefore, the accuracy of the content values in relation to the saturation values displayed are dependent on the accuracy of the user entered sample THb level.

Errors increase at lower oxygen saturations and hemoglobin concentrations, primarily due to handling of the blood samples. The user is cautioned to minimize unnecessary handling of the blood samples.

Repeatability:

Defined as the ability to repeatedly measure the same oxygen saturation of a sample to within the specified limits 68% of the time (one standard deviation).

ABBREVIATIONS: Used in the manual

ART%	Arterial oxygen saturation (percentage)
ART	Arterial oxygen content
AVO_2diff	Arterial venous oxygen content difference
CAL	Calibration
%COHB	Percent Carboxyhemoglobin
ER.?	Error codes- see appendix
LED	Light emitting diode
%Met Hb	Percent Methemoglobin
mg/dl	Milligrams per decaliter
nm	Nanometer, one-billionth of a meter, 10^{-9}
O_2CONT	Oxygen content
O_2SAT	Oxygen saturation
%O_2Hb	Percent oxyhemoglobin
OCC	Oxygen content capacity
OD	Optical Density
PCO	Partial pressure of carbon monoxide
PO_2	Partial pressure of oxygen
%RHb	Percent of reduced hemoglobin
%SAT	Oxygen saturation percentage
SO_2M	Functional Oxygen Saturation
THb	Total hemoglobin , expressed in grams/deciliter
VEN	Venous oxygen content
VEN%	Venous oxygen saturation percentage

EQUATIONS: Used in this manual

Total hemoglobin (THb): $THb = O_2Hb + COHb + MetHb + RHb$

Oxyhemoglobin (O_2Hb): $\%O_2Hb = \frac{O_2Hb}{THb} x100$

Carboxyhemoglobin (COHB) $\%COHb = \frac{COHb}{THb} x100$

Methemoglobin (MetHb) $\%MetHb = \frac{MetHb}{THb} x100$

FUNCTIONAL SATURATION:

Functional saturation is the percent of oxyhemoglobin as it relates to the total hemoglobin available for oxygenation.

$$Functional\%SAT = \frac{\%O_2Hb}{\%O_2Hb + \%RHb} x100$$

or

$$\%SO_2M = \frac{\%O_2Hb}{100 - \%COHb - \%MetHb} x100$$

FRACTIONAL SATURATION:

Fractional saturation relates the amount of oxygenated hemoglobin as compared to all hemoglobins represented within a blood sample, and is expressed as a percentage of total hemoglobin.

$$Fractional\%SAT = \frac{\%O_2Hb}{\%O_2Hb + \%COHb + \%MetHb + \%RHb} x100$$

Oxicom Internal QC Filter Worksheet

Use this worksheet to record your daily Quality Control readings

Oxicom S.N. _____ Month: _____ Page _____ of _____

Filter:	QC1	QC2	QC3
Readings:	____	_____	____
Range:			
From:	____	_____	____
To: (±3%)	____	_____	____

Last calibration:

Location: _____

The daily readings should be within 3 %Sat of the readings entered above. E.g. 60% ±3% can be from 57 to 63 %Sat

Daily record:

Date	QC1	QC2	QC3	Corrective Action	Initial

Inspected sample chamber and cleaned Yes / No (circle)

Date	QC1	QC2	QC3	Corrective Action	Initial

Inspected sample chamber and cleaned Yes / No (circle)

Date	QC1	QC2	QC3	Corrective Action	Initial

Inspected sample chamber and cleaned Yes / No (circle)

Oxicom External Liquid QC Worksheet

Use this worksheet to record your weekly Quality Control readings

Oxicom S.N. _____ Month: _____ Page _____ of _____

Sample Readings:	QCHigh	QCMid	QCLow
	_____	_____	_____
Range:			
From:	____	_____	_____
To: (±7%)	____	_____	_____

Last calibration:

Location: _____

The weekly readings should be within 7 %Sat of the readings entered above. E.g. 52% ±7% can be from 45 to 59 %Sat

Weekly record:

Date	QCHigh	QCMid	QCLow	Corrective Action	Initial

Inspected sample chamber and cleaned Yes / No (circle)

Date	QCHigh	QCMid	QCLow	Corrective Action	Initial

Inspected sample chamber and cleaned Yes / No (circle)

Date	QCHigh	QCMid	QCLow	Corrective Action	Initial

Inspected sample chamber and cleaned Yes / No (circle)

Oxicom 3000 Calibration Worksheet

Oxicom 3000 S.N. _____ Date: _____Name:_____

Read or review calibration instructions for the Oxicom 3000, Sections 4.4.

Obtain blood sample, refer to Section 4.2

Measure functional oxygen saturation and hemoglobin of the blood samples with a co-oximeter.

HIGH Sample (> 90%)

$\%O_2Hb$ = _____

%COHb = _____

%MetHb = _____

$$\%SO_2M = \frac{\%O_2Hb}{100 - \%COHb - \%MetHb} x100$$

$\%SO_2M$ = _____

LOW Sample (60% ~ 70%)

$\%O_2Hb$ = _____

%COHb = _____

%MetHb = _____

$$\%SO_2M = \frac{\%O_2Hb}{100 - \%COHb - \%MetHb} x100$$

$\%SO_2M$ = _____

$\%SO_2M$ = % Saturated O_2 Measured
$\%O_2Hb$ = % Oxygenated Hb
%COHb = % Carboxyhemoglobin
%MetHb = % Methemoglobin

Total hemoglobin: _____

CO-Oximeter used: _____